UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: JUUL LABS, INC. MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

Case No. 19-md-02913-WHO

ORDER ON MOTIONS TO EXCLUDE

Dkt. Nos. 2683, 2686, 2701, 2709

Plaintiffs have identified 26 generic and case specific experts in connection with both the B.B. personal injury bellwether trial and the personal injury claims more generally. Through seven opening briefs, JLI challenges and moves to exclude or strike opinions, in whole or part, of 22 of those experts. Dkt. Nos. 2690-2709. Altria seeks to strike or exclude opinions of eight of those experts. Dkt. No. 2685. The Other Director Defendants (Valani, Pritzker, and Huh, "ODDs") move to exclude or strike opinions of three experts specifically and "other" experts generally. Dkt. No. 2687. The Founder and Director Defendants (Monsees and Bowen) fully join JLI's motions and then raise in passing specific objections to particular opinions of many of the experts. Dkt. Nos. 2712, 2714. The briefing included many hundreds of pages of often repetitious arguments.

This Order deals with all motions except defendants' motions directed to plaintiffs' abatement experts, the defense motions with respect to opinions regarding causation of medical conditions that are not being asserted in the B.B. bellwether personal injury trial, and plaintiffs' motion with respect to Dr. Jeffrey Arnett. Those motions are deferred.[1] I will, initially, address

[1] Plaintiffs moved to exclude only one of the generic defense experts, Dr. Jeffrey Arnett, who testifies generally regarding health risks of JUUL use and comparisons between the health risks of JUUL and traditional combustible cigarettes. Dkt. No. 2727. Arnett is not disclosed as a defense witness for the B.B. trial.

JLI's overarching arguments in six different motions: "Introductory 'Roadmap'" ("Roadmap *Daubert*"); "Brief #1: Omnibus *Daubert* Motion to Exclude Certain Marketing Opinions" ("Marketing *Daubert*"); "Brief #2: Omnibus *Daubert* Motion to Exclude Certain Addiction Opinions" ("Addiction *Daubert*"); "Brief #3: Omnibus *Daubert* Motion to Exclude Certain Opinions on Toxicity and Alleged Health Effects" ("Toxicity *Daubert*"); "Brief #4: Omnibus *Daubert* Motion to Exclude Fact Narrations and Opinions Regarding Intent, State-of-Mind, and Legality" ("Narration *Daubert*"); and "Brief #5: Omnibus *Daubert* Motion to Exclude Opinions on Alleged Failures to Act" ("Failures to Act *Daubert*").[2] I then consider the specific challenges to each of plaintiffs' experts separately. When the arguments on the specific challenges replicate the overarching ones, I summarize my conclusions without repeating the earlier discussion.

I. JLI'S OVERARCHING ARGUMENTS

A. Roadmap

In its Roadmap opening brief and reply, JLI explains its view of the regulatory regimes within which JLI has operated or now operates – most obviously the Tobacco Control Act (TCA) and FDA regulations and guidance issued thereunder – and contends that various experts ignore, misconstrue, or contradict aspects of that regulatory regime. *See generally* Roadmap [Dkt. No. 2701] and Roadmap Reply [Dkt. No. 2889] & Appendix A [Dkt. No. 2889-1]. JLI seeks to exclude opinions that ignore regulatory constraints or that are contradictory to FDA guidance as failing the "fit" requirement that opinions fit the facts of the case. *See, e.g.*, Roadmap Reply at 3.

I have already addressed the legal question of preemption by the TCA and how it impacts the admissible evidence. I generally agree with JLI that no expert may opine at trial that a particular defendant should have taken actions that were specifically prohibited by, or not taken actions that were specifically authorized by, identified federal statutes or regulations. But the opinions offered by plaintiffs' experts do not appear to cross that line or conflict with any of my preemption rulings to date. The parties have, with respect to the upcoming B.B. trial, been

[2] In JLI's opening Roadmap motion, Dkt. No. 2701, JLI lays out the undisputed standards courts apply when considering motions to exclude under *Daubert* and Rule 702. Those undisputed standards are incorporated and applied here.

instructed to meet and confer regarding potential limiting instructions and the boundaries of my preemption rulings as applied to B.B.'s claims.

Defendants' concerns about expert opinions on warnings are, again with specific respect to the upcoming B.B. trial, being addressed through the parties' meet and confer process; I will consider any appropriate limiting instructions. JLI's related objections that plaintiffs' experts failed to consider or appropriately weigh the impact of federal statutes, regulations, or agency guidance go to the weight of that testimony but do not merit exclusion.

JLI's arguments that portions of plaintiffs' experts' opinions should be excluded because they are "contrary to the federal regulatory framework established under the Tobacco Control Act and other federal strictures" are generally rejected. This argument largely stems from JLI's position that given the extensive regulatory authority conferred on the FDA, all JLI was required to do to sell and market its product was place the minimum nicotine warning on its packaging in May 2018. That is incorrect. It ignores my prior limited preemption rulings. Plus, JLI designed and brought JUUL to market before the Deeming Rule went into effect. How and whether plaintiffs' experts considered the "public health" balancing mandated by the FDA under the TCA for tobacco products and ENDS under the Deeming rule can be explored on cross-examination.

I will consider JLI's more targeted objections at trial if plaintiffs' experts testify that JLI's conduct was governed or bound by the regulations imposed on tobacco companies or requirements imposed through the tobacco Master Settlement Agreement ("MSA"). Plaintiffs may avoid the need for the type of limiting instruction discussed in the Order on the motions in limine for the B.B. trial if their experts avoid opining that JLI's conduct was "governed" or "bound" by MSA.

B. Marketing *Daubert*/Brief #1

The heart of JLI's Marketing *Daubert* is that specific experts' opinions regarding marketing and causation, focusing on the purported impact JLI's marketing had on B.B. specifically or youth and consumers more generally, are unreliable and should be excluded. Its criticisms are discussed below.

1. No Empirical Research and No Methodology

JLI challenges the following marketing experts: Dr. Anthony Pratkanis (who primarily

opines on JUUL's "unique selling proposition" or "USP"); Dr. Sherry Emery (who primarily assesses JUUL's unique appeal to youth); Dr. John Chandler (who primarily opines on how JUUL achieved its reach through social media and viral marketing strategies); Dr. Minette Drumright (who opines on the nature and impact of JUUL's marketing and advertising and corporate codes of conduct); Dr. Neil Grunberg (who opines primarily on the addictiveness of JUUL and how JUUL's marketing impacted perception and then use of JUUL); Dr. Bonnie Halpern-Felsher (who opines primarily that defendants failed to act to protect adolescents and youth despite their awareness of JUUL being uniquely attractive to youth); Dr. Robert K. Jackler (who opines primarily that JUUL's branding and marketing were unreasonably attractive to youth); Dr. Sharon Levy (who primarily opines on general issues regarding the addictive properties of JUUL and its impact on youth); Dr. Judith Prochaska (who primarily opines that nicotine exposure during youth is more likely to result in addiction and on the addictiveness of JUUL, as well as the impacts of addiction and use on B.B.); and Dr. Jonathan Winickoff (who opines primarily on the basic science of tobacco and nicotine and the impact of use on youth and B.B.). JLI broadly argues that their opinions should be excluded for the following reasons.

Failure to Conduct Empirical Research. JLI asserts that each of the identified experts' conclusions must be excluded because each failed to conduct any original empirical research about actual consumer perceptions of JLI's marketing: how it impacted youth specifically or consumers more generally. JLI also complains that none of these experts empirically tested whether JLI's marketing and advertising conveyed specific health claims to youth or general consumers or whether JLI did or did not sufficiently convey health warnings about JUUL.

No Basis for their Opinions. JLI complains that instead of conducting new empirical research to support their opinions regarding youth and general consumer impact, plaintiffs' experts rest their opinions about consumer perception on review of others' research and on their subjective interpretations of largely anecdotal but unreliable comparisons to research, studies, experience concerning tobacco companies and the MSA but not concerning ENDS generally or JUUL specifically. As a result, JLI characterizes these experts' opinions as being *ipse dixit* (an assertion without proof) and excludable.

Rule Out Other Causes. Finally, JLI argues that since these experts did not rule out other causes for their alleged health and youth claims (*e.g.*, peer influence on youth uptake and popularity of the product among the adult population), their opinions are unreliable and must be excluded.

In making each of these broad brush arguments, JLI does not focus on the specific types of claims asserted by the different sets of plaintiffs within this MDL. For example, in B.B.'s case and in similar personal injury cases, plaintiffs bring claims for negligence, fraud, failure to warn, and other product defect claims. In the class action, plaintiffs assert claims for fraud, violation of consumer protection statutes, and violation of RICO.[3] In the Government Entity cases, plaintiffs assert claims for negligence, public nuisance, and RICO.

In the Marketing *Daubert*, JLI fails to demonstrate that any particular claims within this broad MDL *require* specific types of empirical evidence to admit these experts' opinions regarding the impact of JUUL's marketing. Plaintiffs persuasively show that for some of the claims, the testimony of the plaintiffs (what they saw and understood) and a reliable expert opinion (based on literature review, the expert's experience, and JLI's own documents regarding what JLI's marketing and advertising materials were meant to convey or did convey) can suffice to provide evidence of causation and reliance by a particular plaintiff or a "reasonable" objective plaintiff where required.[4] JLI may, as the MDL progresses and different types of claims are presented through bellwether trials, raise case-specific arguments that empirical evidence is required to prove specific types of claims. But that showing has not been made here generally or with respect to B.B.'s upcoming trial under Tennessee law. *See, e.g., Krommenhock v. Post Foods, LLC*, 334 F.R.D. 552, 565 (N.D. Cal. 2020) (rejecting argument that "reasonable consumer" determination under California law required consumer survey evidence; "[i]nstead, testimony from plaintiffs' marketing expert [] – relying on his extensive experience in the

[3] The Racketeer Influenced and Corrupt Organizations Act ("RICO").

[4] Pratkanis, for example, relied on defendants' own marketing research. Pratkanis Report (Dkt. No. 2699-6) at 13 (citing Altria-received market research survey showing that "70% of all users and 78% of current users believe JUUL is healthier than smoking").

industry, including marketing of cereal products, and Post's own documents – as well as the models developed by Gaskin and Weir, support that the Challenged Statements could have been material to the reasonable consumer.").

JLI broadly argues that the challenged marketing experts lacked any methodology to support their opinions regarding the purpose and impact of JLI's marketing efforts. But the question is whether these marketing experts' experience, review of relevant literature (including publications from government bodies), and review of JLI's own documents provide a reasoned and reliable basis for their disputed testimony. Generally, I find that their methodologies are sufficient. By his or her experience, review of relevant literature, and review of the record in this case, each of the experts identified above is able to opine generally about both JLI's health messaging and its impact as well as JLI's youth messaging and its impact.[5]

JLI is correct that many of these experts' past experiences have been centered in the tobacco industry – in terms of regulatory analysis, researching and publishing on the history of and current trends or limitations on marketing and advertising, and other tobacco-marketing topics – and many only recently have gained experience with ENDS generally and JUUL specifically. That does not make their opinions excludable. These experts have explained why their past experiences with the tobacco industry provide a relevant basis for their opinions about ENDS. Those connections and whether that experience is transferrable in whole or part from the tobacco-industry to the ENDS-industry are strongly disputed by defendants. But there is enough logical connection that defendants' complaints go primarily to the weight of these experts' opinions and not their exclusion.

2. Design

Grunberg, Jackler, Prochaska, Shihadeh, and Winickoff opine that design elements of

[5] JLI's arguments that these experts failed to consider documentary evidence and studies that JLI contends contradict their opinions and that some experts only reviewed "cherry-picked" evidence or restricted their review to only a limited set of JLI's campaigns go to the weight of these experts' opinions and do not justify wholesale exclusion. Similarly, while some of these experts' opinions approach the outer-boundaries of their experience, it is unclear whether plaintiffs intend to rely on those portions of the opinions at trial. JLI may bring more targeted, precise objections at trial if plaintiffs solicit opinions that stretch the boundaries of these experts' experience.

JUUL (the flavors, the "smooth nicotine" salt formula, and the sleek and easily concealable design) targeted or "uniquely" appealed to youth. JLI challenges these opinions because they lack sufficient facts, data, or methodology, and do not rule out alternate causations (*e.g.*, peer influence, adolescents who engage in risky behavior). It complains that these experts conducted no empirical analyses or independent research to support their conclusions and that their *ipse dixit* opinions regarding the design and youth-appeal of JUUL do not adequately account for legitimate adult-focused design factors. Those criticisms go to weight, not admissibility. These experts' opinions are generally admissible given their experience in marketing, their specialties or focus on the tobacco and now ENDS industries, and their reliance on their own or others' empirical research.[6] JLI may cross-examine them on their consideration of, or failure to consider, alternate or contributory causes. As noted elsewhere, experts on both sides must be cautious when approaching ultimate issues of causation that might – depending on the claims at issue in particular trials – invade the province of the jury.

JLI also attacks the opinions of Shihadeh, Winickoff, Grunberg, and Prochaska that other design features should have been but were not incorporated in JUUL to prevent youth appeal or use. JLI contends that those opinions are based only on speculation and in some instances were not feasible, or reasonable, or permissible after the FDA issued the Deeming Rule. What JLI could have done or should have done, consistent with developing technology as well as FDA regulations or guidance before or after the Deeming Rule went into effect, are issues that are subject to vigorous disagreement between the parties. These objections, at most, provide ground for cross-examination, not exclusion.

3. Causation

JLI contends that none of the plaintiffs' experts' opinions that its marketing and its design choices caused the youth vaping epidemic is substantiated using a reliable and replicable methodology. In large part this argument hinges on the alleged lack of independent empirical

[6] For example, Winickoff relied on Ramamurthi et al., 2018. Winickoff Report [Dkt. No. 2700-1] at 184. Grunberg conducted his own empirical analysis in 2018, as well as relying in JLI's own studies and documents. Grunberg Report [Dkt. No. 2690-11] at 107-09.

research argument addressed above, but also on JLI's characterizations of plaintiffs' experts as having failed to review contrary evidence and to account for alternative causation. JLI notes that its expert (Rossi) performed an empirical analysis to determine and opine that youth use was linked to growing adult sales rather than JLI's advertising and design. These arguments raise grounds for cross-examination and are "battle of the experts" disputes to be resolved by the jury.[7]

JLI also contends that plaintiffs' experts cannot "prove causation" due to JLI's "viral" social media presence as, according to JLI, the majority of social media content analyzed by plaintiffs' experts was generated by third-parties outside of JUUL's control. JLI argues that plaintiffs' experts failed to use an established methodology to measure and establish virality and then failed to support the causative-connection between JLI's own marketing and the third-party content. It claims that its expert (Berger) "disproves" the opinions of Chandler, Emery, Woolley, and Jackler that JLI caused the spike in youth uptake through their intentionally viral social media efforts. However, the challenged experts have significant expertise in marketing, particularly social media marketing, and provide opinions on how JLI effectively and intentionally "seeded" social media with youth-appealing messages in order to have that content picked up and disseminated by third-parties, like celebrities and social media influencers. At base, this again is a battle of the experts to be resolved by the jury, with – as contemplated for the B.B. trial – potential

[7] Defendants' cases excluding expert opinions for their failure to perform epidemiological analyses and rule out alternative causation arise almost exclusively in the medical injury context. Those cases are inapposite for the challenged *marketing* testimony. *See, e.g., Casey v. Ohio Med. Prod.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (rejecting study that "clearly does not describe[] an epidemiological analysis" but instead is "simply a compilation of case reports" as not "reliable scientific evidence of causation, because they simply described reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation."); *see also Metabolife Int'l, Inc. v. Wornick*, 264 F.3d 832, 840 (9th Cir. 2001) (finding district court erred when it excluded "all of its scientific evidence regarding the *safety* of Metabolife 365 when used as directed") (emphasis added); *Liaw v. United Airlines, Inc.*, No. C 19-00396 WHA, 2019 WL 6251204, at *4 (N.D. Cal. Nov. 22, 2019 (excluding speculative opinions on cause of medical injury based only on correlation between two "abnormal" events). The relevant question here – at the *Daubert* stage – is whether the marketing experts' bases for their opinions on causation are sufficiently reliable for admission. *See, e.g., Obrey v. Johnson*, 400 F.3d 691, 696 (9th Cir. 2005) ("As a general matter, so long as the evidence is relevant and the methods employed are sound, neither the usefulness nor the strength of statistical proof determines admissibility under Rule 702."). To the extent future admissibility determinations turn on the particular claims being asserted under specific state laws, those issues may be raised at summary judgment or on case-specific *Dauberts* going forward.

limiting instructions that JLI can only be held liable based on its own conduct including, as alleged by B.B., that JLI's own conduct had foreseeable consequences upon B.B.

As this discussion shows, how and where causation fit into each case will depend on the claims raised. How far experts will be able to opine regarding causation depends on the same. Generally, even if an expert cannot definitely prove that aspects of defendants' conduct caused something, that does not mean that testimony is excludable. *See, e.g., Ambrosini v. Labarraque*, 101 F.3d 129, 135 (D.C. Cir. 1996) (expert's evidence "does not warrant exclusion simply because it fails to establish the causal link to a specified degree of probability. The fitness prong of the *Daubert* admissibility inquiry primarily concerns relevance."); *see also In re High-Tech Emp. Antitrust Litig.*, No. 11-CV-02509-LHK, 2014 WL 1351040, at *24 (N.D. Cal. Apr. 4, 2014 ("neither Rule 702 nor Daubert requires that an expert's testimony, in part or in whole, singlehandedly prove an element of the offering party's case for it to be admissible.").

4. B.B. Specific Opinions.

JLI first reiterates an argument made on summary judgment, that because B.B. admitted that she never really paid attention to warnings or advertisements, she cannot prove causation based on her own testimony. That allegedly makes the case-specific expert testimony about the impact on B.B. unreliable. Beyond that already-rejected argument, which does not support exclusion of any identified B.B.-specific expert testimony, JLI also contends that the B.B.-specific experts (Prochaska, Levy, Grunberg, and Winickoff) do not have reliable foundations for their opinions because they rely on anecdotal evidence, contradict prior opinions, or insufficiently identify sources for their B.B.-specific opinions. Those are grounds for cross-examination, not exclusion.

5. Youth-Prevention Opinions

Finally, JLI argues that the opinions from Halpern-Felsher, Drumwright, and Jackler on youth-prevention efforts that JLI should have undertaken are excludable because they are irrelevant (to the extent they based on the MSA that did not bind JLI) and because these experts are not qualified to opine on prevention related to vaping (as opposed to tobacco where their past expertise resides), or age verification methods. Those objections do not justify exclusion.

Plaintiffs admit that youth prevention measures are not the focus of these experts' opinions; their focus instead is that JLI's marketing led to the youth vaping epidemic. Pls. Omnibus Oppo. at 83-84. A limiting instruction may be provided if plaintiffs' experts stray too far and testify or imply that the MSA was legally binding on JLI. But the experts on both sides may testify to what extent and how the MSA guidelines could have or should have guided JLI. Moreover, these experts are largely qualified to discuss prevention and age verification issues based on their experience with youth tobacco use prevention efforts; JLI can cross-examine on the relevance of that experience to ENDS use and ENDS youth prevention efforts.[8]

C. Addiction *Daubert*/Brief #2

JLI argues that plaintiffs' nicotine, addiction, and abuse liability experts' opinions must be excluded because they: (i) applied the wrong standard in comparing abuse liability (by failing to compare JUUL to combustible cigarettes); (ii) did not follow accepted methods to make their abuse liability assessments; (iii) made opinions outside of the TCA framework for abuse liability; and (iv) opined that abuse liability of JUUL products is greater than for cigarettes, which is not supported by reliable science.[9]

1. Wrong Standard

JLI contends that given the requirements of the TCA and the FDA regulations regarding what applicants for new tobacco products have to show in their Premarket Tobacco Product Applications ("PMTA"), the abuse liability or addictiveness of JUUL must be assessed by balancing the risks and benefits of new products' use with the end goal of protection of the public's health. It asserts that JUUL must be assessed as a "switching product" – meaning a product designed to capture existing tobacco product users – as opposed to a "cessation product" –

[8] Plaintiffs note that Drumwright did not opine specifically about the adequacy of JLI's age-gating systems, but relied on her observation that JLI did not appear to be increasing its age verification steps when it launched the product. That is a topic for cross-examination. If Drumwright, Halpern-Felsher, or Jackler venture into opinions on the adequacy of JLI's age-gating steps more generally, as opposed to the need for age-gating when selling products containing nicotine, JLI is free to object at trial that those opinions stray too far from their particular areas of expertise.

[9] JLI moves to exclude opinions of Dr. Thomas Eissenberg, Dr. Neil Grunberg, Dr. Alan Shihadeh, and Dr. Jonathan Winickoff, as outlined in its Appendix A, Dkt. No. 2889-1, through its Addiction *Daubert*.

meaning a product designed to wean tobacco product users off of their tobacco or nicotine habits. JLI contends that plaintiffs' experts must analyze JUUL as a replacement for cigarettes and not a tool for quitting nicotine altogether. Under that analysis, the relevant abuse liability determination for adult smokers would compare the addictiveness of JUUL products against cigarettes while the relevant abuse liability determination for current ENDS users would be between JUUL and other ENDS products.

JLI complains that plaintiffs' experts do not provide an analysis of what, if any, abuse liability would be appropriate to help switch adult smokers, focusing instead on other inapposite issues like the risk of an attractive product like JUUL being taken up in the first instance by a child. It also complains that plaintiffs' experts should not have looked to nicotine cessation products as proper comparators and should not be allowed to testify that JUUL should have and could have been designed as a cessation device. *See* Addiction *Daubert* at 7-8 (identifying testimony from Prochaska and Shihadeh).

The failure of a particular expert to engage in what JLI argues is the appropriate abuse liability standard for a new tobacco product (as required by the FDA under a PMTA application) does not mean that the experts' abuse liability determinations are incorrect, preempted as a matter of law, prejudicial, or otherwise excludable. JLI has not shown – in light of the claims at issue in this MDL generally or B.B's specific claims – that plaintiffs' experts were required to conduct the same assessment that the FDA is conducting on JUUL's PMTA. Instead, plaintiffs' experts' opinions on addictiveness are based on a range of studies and tests and consider different aspects of JUUL (including its design, the method of nicotine delivery, the flavors offered, and methods of consumer use). These are clearly relevant to the range of claims at issue. JLI will be free to argue at trial that these experts' opinions are undermined by their alleged failure to compare JUUL to cigarettes or other ENDS as "switching products" with the goal of reducing overall harms to public health presented by traditional tobacco products.

Similarly, the testimony by these experts that JLI could have designed a device to work as a cessation device or employed a safer design to reduce or eliminate risks of harm is not excludable. As plaintiffs point out, most if not all of JLI's design choices were made prior to the

promulgation of the Deeming Rule (meaning prior to any FDA regulation). JLI is free to argue that it was guided by existing FDA regulations. But for the requirements the FDA has put into place, JLI has not shown that categories of claims are preempted (other than consumer protection claims based on nicotine addiction warnings in light of the FDA's minimum warning). This testimony is clearly relevant to B.B.'s and presumably other plaintiff's product liability claims.

JLI argues that science does not support plaintiffs' experts' opinions that lower nicotine can effectively switch smokers away from combustible cigarettes, relying in part on JLI's interpretation of those experts' own publications and JLI's interpretation of other publications. This is a classic example of a dispute that is subject to debate and appropriate for cross-examination, not exclusion.

JLI also contends that expert opinions that JUUL is too addictive for youth do not fit because they rest on the same erroneous reading of the TCA (that JUUL should be considered only as a switching device for adults, not a cessation device) and will only serve to confuse the jury because all parties agree that products containing nicotine are too addictive for youth. As noted, JLI is incorrect that the TCA required plaintiffs' experts to assess abuse liability only as a switching product, given the claims in the MDL generally and B.B.'s case in particular. Moreover, that all parties agree that nicotine devices are inappropriate for youth does not mean those opinions should be excluded. JLI's last arguments – that plaintiffs' experts have "not identified anything about the addictiveness of JUUL products that was youth specific and unimportant to the mission of switching adult smokers" and ignored that flavors are important to switch adult smokers – overlook plaintiffs' claims (supported at this stage by expert opinions, disputed by JLI) that aspects of JUUL's design including the flavors offered were "uniquely appealing" to youth. These are topics for cross-examination, not exclusion.

2. Abuse Liability Assessments

JLI challenges plaintiffs' experts' opinions that the abuse liability of JUUL is higher than combustible cigarettes because: (i) the experts agree that pharmacokinetic (PK) studies show comparable results for JUUL and cigarettes; (ii) the experts have not shown through "dependence measures" that JUUL products are more addictive than cigarettes; and (iii) Shihadeh's opinions on

adult JUUL users being moderate to highly dependent on the product was reached without a reliable methodology. These arguments – when considered in the full context of the experts' reports and opinions – are disputes between the experts and raise grounds for cross-examination, not exclusion.[10]

JLI additionally challenges reliance by plaintiffs' experts on types of behavioral use of JUUL (pod "popping" and "squeezing" the pod) that allegedly increase addiction potential, arguing that those comparisons are irrelevant and excludable because: (i) they are based on the wrong standard (failing to compare similar forms of abuse in cigarettes or competitor ENDS); (ii) they ignore that some other ENDS may be subject to similar or greater misuse; and (iii) the opinions that JUUL creates a "variable reinforcement" issue – as a result of delivering differing amounts of nicotine depending on user "misuse" – are unsupported because the experts agree that at least some nicotine is delivered with each puff, although user "misuse" can increase the delivery of nicotine. Each of these arguments goes to the weight the jury may give the experts' opinions and raise grounds for cross-examination, not exclusion.

JLI's overarching arguments for exclusion in its Addiction *Daubert* fail.

D. Toxicity *Daubert*/Brief #3

JLI moves to exclude all of plaintiffs' experts' opinions on non-addiction health-risks for all claims, as well as the case-specific opinions as to B.B. Specifically, JLI moves to exclude opinions: (i) that the chemical constituents, including nicotine, in JUUL's aerosol are toxic; (ii) that use of JUUL causes non-addiction health effects; (iii) about the impact of nicotine on the developing brain or the psychological impact of addiction; and (iv) that use of JUUL caused

[10] To the extent that JLI argues that plaintiffs' experts were required to conduct a "formal" Abuse Liability Assessment to provide opinions on the addictiveness of JUUL, as JLI did in support of its PMTA, that argument is unfounded. Plaintiffs' experts performed analyses in support of their opinions and reviewed testing performed by others, including JLI. Shihadeh Report [Dkt. No. 2699-12], Section 4 "Analysis"); Prochaska Report [Dkt. No. 2699-7], Sections 6 ("JUUL's Nicotine Salt Pod Devices: Easy to Inhale & Highly Addictive"), 7 (opinions on JLI commercialized products with design features that allowed "spiked nicotine levels"), 8 (use of benzoic acid to reduce harshness), 9 (non-tobacco flavors appeal to youth and increase abuse liability). This work, in combination with their unchallenged expertise and experience, is sufficient.

B.B.'s non-addiction injuries and/or justifies medical monitoring damages.[11]

Plaintiffs have clarified that B.B. is no longer seeking damages related to non-addiction health effects or anything not related to her nicotine use. *See* February 23, 2022, Transcript [Dkt. No. 2920] at 10. B.B. has also dropped her stand-alone claim for medical monitoring, although she reserves the right to seek medical monitoring damages as a result of her nicotine addiction. *See* February 16, 2022, Transcript [Dkt. No. 2901] at 46. As such, I will defer ruling on JLI's motion to exclude medical and causation opinions regarding health effects not related to use of nicotine including seizures, asthma, EVALI,[12] GERD,[13] and "other respiratory" conditions (bronchitis, emphysema, and COPD). Toxicity *Daubert* at 18-20. Only the health impacts related to B.B.'s addiction to nicotine will be addressed.

1. Non-Addiction Health Risks/Dose

JLI argues that plaintiffs' experts have no basis for generally asserting that JUUL products are capable of causing non-addiction health risks because there are no "epidemiology studies" focused on JUUL or for most ENDS. Absent those epidemiology studies, plaintiffs' experts are left with only toxicity and chemical analyses, but those efforts fail according to JLI because the experts never addressed dose.

JLI asserts that plaintiffs' experts Tackett and Pue failed to address whether constituents they claim are toxic are present in JUUL aerosol in "toxic doses," meaning that the levels users were exposed to are sufficient to reach the threshold at which the substance is toxic. JLI contends that the mere fact that chemicals might be present in JUUL aerosol is insufficient without dosage analysis because the mere presence of a chemical does not make it toxic at all doses.

As an example, JLI notes that while Tackett identifies the presence of two chemicals in JUUL aerosol as sources of harm – vanillin and methylglyoxal – he did not do his own calculation

[11] As outlined in its Appendix A, Dkt. No. 2889-1, through its Toxicity *Daubert*, JLI moves to exclude opinions of Dr. Alicia Casey, Dr. Thomas Eissenberg, Dr. Neil Grunberg, Dr. Halpern-Felsher, Dr. Sharon Levy, Dr. Judith Prochaska, Dr. Charles Pue, Dr. Randall Tackett and Dr. Jonathan Winickoff.

[12] EVALI stands for e-cigarette or vaping associated lung injury.

[13] GERD stands for gastroesophageal reflux disease.

on vanillin in JUUL's aerosol and there is no established recommended exposure limit for methylglyoxal. JLI dismisses Tackett's attempt to extrapolate limits for methylglyoxal from others' studies as unsound, contending that one of the studies Tackett relied on has numerous "deficiencies" and the other tested at a dose far exceeding that in JUUL. For the third chemical discussed by Tackett, diacetyl, Tackett admitted that there are no health-based standards for diacetyl inhalation and his attempt to create one failed to compare his standard to how much diacetyl was present in JUUL aerosol.

JLI moves to exclude Pue's opinions on similar grounds. It contends that Pue admitted that there are no "threshold" levels at which the various chemicals he opines are present in JUUL vapor cause any of the lung diseases in his report. JLI also argues that Pue's admissions that he omitted calculations from his report and his reliance on Tackett's unreliable methylglyoxal calculations are reasons to exclude Pue's opinions.

These objections do not require exclusion. Tackett relied on numerous studies – including studies JLI cites in its PMTA – that show that e-cigarette use caused respiratory disease and identify by amount the presence of various chemicals. *See, e.g.*, Tackett Report at 21-27. Pue relied on Tackett. That Tackett did not conduct his own calculations for many of the chemicals he discusses is not a ground to exclude. Tackett relied on other publications that did indicate dose information (or information from which dose could be calculated) and Tackett performed his own dose analysis for methylglyoxal. JLI's criticisms about Tackett's and Pue's failures to establish limits for appropriate levels of methylglyoxal and other toxins – particularly Tackett's use of the "conservative" diacetyl limit for the "more-toxic" methylglyoxal – is a matter for cross-examination (that certain levels of these toxins may not be harmful), not exclusion.

JLI then challenges Tackett's and Pue's assertions that combinations of chemicals may have had an "additive" effect making their presence toxic, because those assertions are based only on a generally established tenet of toxicology and not on any study they conducted. The studies that Tackett and Pue relied on, according to JLI, are inapposite because they address ENDS generally but not JUUL aerosol specifically, and do not discuss the particular constituents that are in JUUL in the doses delivered by JUUL. Relatedly, JLI argues that Tackett's and Pue's failures

to acknowledge the mixture studies that were performed by JLI in support of its PMTA further makes their additive opinions unreliable and subject to exclusion.

Tackett's and Pue's additive opinions will not be excluded. They explained the bases for their opinions identifying chemicals that, when added together, increased the risk of harm (*e.g.*, by allowing the chemicals to go deeper into users' lungs, naming combinations that can create carcinogenic toxins). JLI is free to argue – based on its experts' opinions – that the mixing of chemicals could have an antagonistic as opposed to an additive or synergistic effect.

2. Comprehensive Risk Assessment

JLI also points to the studies that it conducted in connection with its PMTA comparing health risks from its products (as well as competitor ENDS) to combustible cigarettes: those studies concluded that JUUL presented much lower risks generally. JLI also notes that the FDA's guidance to PMTA applicants recommends that applicants conduct various studies and explains that while "existing literature" could be relied on, the applicants had to show that the existing data is applicable to their "new tobacco product." JLI criticizes plaintiffs' experts for not attempting to replicate JLI's PMTA testing or conducting their own studies.

As an initial matter, JLI has not shown that plaintiffs' experts were required to complete the same sort of comprehensive risk assessment that JLI completed for its PMTA in light of the elements of the claims asserted under federal and state laws by various groups or sets of plaintiffs in this MDL. This criticism goes at most to weight, not admissibility. JLI will be free to explore with plaintiffs' experts why what JUUL did as part of its PMTA – prepared years after its product was on the market – was not replicated by plaintiffs' experts and to elicit plaintiffs' experts' thoughts on the studies and evidence that JLI submitted with its PMTA.

3. Nicotine Toxicity

JLI also challenges plaintiffs' experts' opinions on nicotine toxicity as not based on reliable evidence, contending that no empirical evidence has demonstrated that nicotine is "toxic" or causes any chronic health conditions, and that the studies relied on by plaintiffs' experts consider instead harms from smoking combustible cigarettes. The vast bulk of JLI's objections are based on cherry-picking some of the experts' opinions that do associate discrete harms from

cigarette smoking to vaping, but JLI ignores those experts' opinions about nicotine outside of its presence in tobacco products. JLI also broadly contends that various experts did not identify the specific scientific support for their assertions or that they relied on "weak associations" from "select" or "preliminary" studies or inapposite animal studies. Toxicity *Daubert* at 13-14. But JLI essentially admits that there is science supporting nicotine toxicity. *Id*. at 16 (characterizing the scientific view regarding nicotine as having changed "very little" since the 1960s). Whether JLI is correct that the bulk of science supports its view and not plaintiffs' view is a matter for the jury.

JLI contends that there is no reliable science to support unidentified experts' opinions regarding "acute effects" from nicotine or Winickoff and Grunberg's opinions regarding "chronic effects" of nicotine and cardiovascular risks. But as JLI acknowledges, these experts identified the sources of those opinions. Whether there are fewer impacts from e-cigarettes compared to tobacco cigarettes is a matter for cross-examination, not exclusion.

Finally, JLI says that plaintiffs have failed to show that the level of nicotine in JUUL pods or the dose provided to a reasonable user (as opposed to an undefined large dose that is unlikely to be experienced by a typical user) is toxic or causes chronic health effects. But JLI admits that there is disputed evidence regarding "acute adverse effects of nicotine." Plaintiffs' experts have explained how JUUL users were able to use JUUL devices to receive larger amounts of nicotine. *See supra*. This argument goes to weight and does not justify exclusion of any particular expert's opinions.[14]

4. Causation for Non-Addiction Risks

In what is a more typical type of *Daubert* challenge, JLI challenges whether plaintiffs' experts have reliable scientific support under the Bradford Hill factors[15] or otherwise that link

[14] JLI repeats its argument from the Marketing *Daubert* that plaintiffs' experts failed to engage with the analysis conducted by the FDA in reviewing a PMTA, namely "whether JUUL products are appropriate for the protection of public health" considering benefits and risks to smokers, former smokers, and nicotine naïve users. Toxicity *Daubert* at 17-18. As already explained, the standard the FDA applies in its PMTA decisions is not conclusive in this case (although it is relevant to the extent it might be considered an industry standard). At most, it provides a ground for cross-examination, not exclusion.

[15] The Bradford Hill factors are discussed in more depth in connection with JLI's motion to exclude the opinions of Dr. Anthony Pratkanis below.

JUUL use to health conditions, specifically: (i) Cardiovascular; (ii) Seizure; (iii) Asthma; (iv) EVALI; and (v) GERD. These conditions/risks have been disclaimed by B.B. as sources for her injuries and damages. The parties agree that determination of whether plaintiffs' experts have sufficient support for a causal link between JUUL use and these specific conditions should be deferred until a bellwether plaintiff intends to offer that evidence at trial.

It is unclear, however, the extent to which B.B. may introduce evidence about injury to her lungs and "other respiratory conditions" as symptoms from her JUUL use and not as separate bases for damages. Assuming that Tackett's and Pue's opinions challenged by JLI that JUUL use can damage lungs or have negative consequences for respiratory health will not be introduced by B.B. in her trial, I will not address them here.[16]

5. Impact of Addiction on Brain Development

JLI challenges the basis for Winickoff's and Levy's assertions that adolescent JUUL use can impair brain development, arguing that they failed to present any reliable methodology for those opinions. It says that Winickoff relied only on animal studies (without explaining how those can be extrapolated to juvenile humans) and Levy relied solely on studies regarding cigarettes (that are allegedly inapposite because cigarettes have a host of other potentially harmful constituents not present in JUUL). However, Winickoff and Levy relied on more than the few studies JLI isolates and attacks in its motion to exclude. And even the studies identified by JLI provide grounds for cross-examination, not exclusion.

6. Psychological Impact of Addiction.

JLI contends that Prochaska, Levy, and Grunberg fail to present "reliable" scientific evidence regarding the psychological impact and behavioral impacts of nicotine addiction (including anxiety disorders, mood disorders, and disruptive behavior disorders), such that JUUL use can be shown to have caused those disorders as opposed to those disorders increasing the likelihood of nicotine abuse. Not so. Each of these experts has identified a sufficient basis to

[16] Pue is not identified as a witness on B.B.'s April 25, 2022, submission and Tackett is not identified as a "likely" expert. Dkt. No. 3062-5.

opine on the impact of chronic nicotine exposure to adolescent brain development and resulting psychological impact.

7. B.B. Specific Arguments

JLI also moves to exclude the opinions that plaintiffs' experts intend to offer at B.B.'s trial regarding symptoms that she alleges she suffered due to her JUUL use and resulting nicotine addiction.[17] JLI contends that each of the experts fails to establish the "specific causation" required for the conditions B.B. complains of related to her nicotine addiction because those conditions preexisted her use of JUUL or because the experts failed to rule out other causes, as required for specific causation.[18]

a. Headaches

JLI challenges Winickoff's opinion that B.B. suffered from more frequent headaches due to her JUUL use because it is based only on self-reports without supporting evidence in her medical records and is not based on reliable scientific evidence because Winickoff relied on inapposite tobacco studies for causal support. Winickoff's B.B.-specific report documents the evidence regarding B.B.'s headaches and provides a basis for him to distinguish between the types

[17] The B.B.-specific opinions of Casey and Levy challenged by defendants will not be addressed, as neither of them are disclosed as witnesses for the B.B. trial. Dkt. No. 3062-5. As noted above, B.B. "decided to withdraw the claims for damages based on asthma exacerbation and on GERD." Tr. 2/25/2022 Hearing at 9-10. It is unclear whether B.B. still intends to present evidence of her "respiratory issues of difficulty breathing and shortness of breath," Pls. Omnibus Oppo. at 125, although she has disclaimed them as a separate basis for damages. JLI challenges Winickoff's opinions that B.B.'s JUUL use could have caused respiratory issues because B.B.'s lungs were "always clear," she had a normal pulmonary function test in 2021, and Winickoff failed to rule out B.B's obesity and acid reflux as contributory causes. Toxicity *Daubert* at 26. I do not reach the issue here, but if B.B. intends to present evidence regarding non-asthma respiratory issues at trial, JLI may reraise this argument. I note that there appears to be significant evidence (some acknowledged in JLI's PMTA submission) that use of ENDS generally has been shown to cause or exacerbate respiratory issues. *See* JLI Rely Br. #3 [Dkt. No. 288303] at 4 n.3.

[18] *See, e.g., Hardeman v. Monsanto Co.*, 997 F.3d 941, 965 (9th Cir. 2021) ("To establish specific causation, experts needed to show that [plaintiff's condition] was caused by [challenged substance], rather than some other factor." To do so, experts use "'differential diagnosis,' which starts with ruling in 'all potential causes, then rul[ing] out the ones as to which there is no plausible evidence of causation, and then determin[ing] the most likely cause among those that cannot be excluded.'" *Id.* (quoting *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1234 (9th Cir. 2017). But in the Ninth Circuit, it is not required "that an expert be able to identify the sole cause of a medical condition in order for his or her testimony to be reliable. It is enough that a medical condition be a substantial causative factor." *Messick v. Novartis Pharms. Corp.*, 747 F.3d 1193, 1199 (9th Cir. 2014).

of headaches B.B. suffered prior to her JUUL use and those suffered after she became addicted to JUUL, linking the post-addiction headaches to her nicotine addiction. *See, e.g.*, Winickoff B.B. Report [Dkt. No. 2700-4] at 4. That Winickoff relies in part on research discussing tobacco products and headaches – and whether that existing research is persuasive in the context of e-cigarettes – can be explored on cross-examination. *See also* Winickoff Generic Report [Dkt. No. 2700-1] at 14 ("Nicotine withdrawal can cause headaches, insomnia, irritability, anxiety, and depression, and these withdrawal symptoms are one of the primary reasons a nicotine addiction is very difficult for my patients to overcome.").

b. Depression/Anxiety/Mood Swings

JLI challenges the opinions of Winickoff and Prochaska regarding whether B.B. suffered or suffers from depression, anxiety, and mood swings caused by nicotine addiction from her JUUL use. The essence of JLI's challenge is the same; there is no evidence that B.B. has received "clinical diagnoses" of chronic depression, anxiety, or mood swing disorders.

Depression. JLI challenges Winickoff's testimony regarding B.B.'s symptoms of depression and his diagnoses that she suffered from "moderate depression" because: (i) B.B. never received a clinical diagnosis of depression; (ii) medical records indicate that she only had one significant depressive episode for which she sought medical treatment in December 2018; and (iii) even Winickoff could only say that B.B.'s symptoms and behavior were consistent with "moderate" depression and acknowledged that diagnosis should be confirmed with additional testing.

Anxiety. JLI attacks Winickoff's and Prochaska's opinions that B.B. has moderate anxiety caused by her nicotine addiction from her use of JUUL because B.B. never received a clinical diagnosis of an anxiety disorder. Even Winickoff's examination diagnosis of "moderate anxiety" was followed by a recommendation to confirm with further testing.

Mood Swings. JLI challenges Winickoff and Prochaska's opinions that B.B. suffered from mood swings due to her JUUL use/nicotine addiction because there is no evidence that B.B. "suffers from mood swings of any clinical significance." Toxicity *Daubert* at 27.

Despite these challenges, JLI does not show or even attempt to show that under Tennessee

law a plaintiff must demonstrate that she received a "clinical diagnosis" or even contemporaneous diagnoses of disorders in order to recover for her experience of symptoms of those conditions in a personal injury case.[19] The question is whether there is sufficient evidence of the existence of those symptoms and a causal link to B.B.'s JUUL use/nicotine addiction. B.B. testified in her deposition that she suffered from depression and anxiety – that she had not really suffered before using JUUL – and that she gets more irritable and anxious and experiences mood swings when she does not have access to nicotine. B.B. Deposition Tr. [Dkt. No. 2700-33] at 124:16-18; 126:8-22; 199:11-18.

Both Winickoff and Prochaska then identify why – based on their general experience, the research to date, their review of B.B.'s medical records, and their examinations of B.B. – they believe B.B. suffered from symptoms of depression, anxiety, and mood swings caused by or contributed to by her nicotine addiction/JUUL use.[20] While Winickoff and Prochaska acknowledge that these symptoms can also be caused by other things in teenagers lives, their opinions are that in B.B.'s case it was her nicotine addiction/JUUL use that caused and contributed to those symptoms. Those opinions may be challenged by JLI at trial, but they will not be excluded.

c. Inability to Concentrate/Cognitive Impairment[21]

JLI contends that – for the same reasons as just discussed – Winickoff's opinions that B.B.'s nicotine addiction/JUUL use caused an inability to concentrate must be excluded because there is no history of a diagnosis of cognitive impairment and Winickoff did not perform a formal ADHD screen. As above, there is ample scientific evidence that nicotine addiction/withdrawal

[19] *See Guthrie v. Ball*, No. 1:11-CV-333-SKL, 2014 WL 11581410, at *18 (E.D. Tenn. Oct. 10, 2014) ("Treating physicians, such as Defendant, may reasonably rely on a patient's self-report of an injury for the purpose of making a diagnosis. *See* Fed. R. Evid. 703.").

[20] JLI does not challenge Winickoff's or Prochaska's general opinions – based on their experience and review of studies and reports – that nicotine addiction and withdrawal can cause depression, anxiety, and mood swings.

[21] JLI also challenges Levy's opinions as to Inability to Concentrate/Cognitive Impairment and Social/Academic decline. Toxicity *Daubert* at 28-29. Levy's B.B.-specific opinions are no longer at issue.

can cause cognitive impairments and an inability to concentrate. Winickoff and Prochaska have adequately identified the bases for their opinions that B.B.'s addiction impaired her ability to concentrate and impacted her cognitive abilities. JLI may challenge those opinions at trial.

8. B.B.'s Medical Monitoring Damages

B.B. has dropped her independent "medical monitoring" claims but still seeks damages for "medical monitoring" related to her nicotine addiction. JLI contends that B.B. has failed to show that she would need any examinations specifically due to her JUUL exposure because she already receives examinations for her current conditions (asthma, heart disease, depression, and GERD) as part of her ordinary care. JLI also asserts that there is no evidence or likelihood that B.B. would suffer new conditions or that those conditions would result from JUUL use as opposed to use of cigarettes or cannabis.

The motion to exclude on this ground is DENIED. Whether sufficient evidence is admitted for B.B. to seek an award of damages for medical monitoring related to claims that the jury finds in her favor should be determined at the close of evidence. JLI has not shown that under Tennessee law these sorts of damages are not allowable under the TPLA or other claims left at issue. B.B.'s likely testifying experts may opine on how different or separate examinations or medical interventions may be necessary for B.B. as a result of her JUUL use/nicotine addiction.

E. Narrative *Daubert*/Brief #4

JLI raises a series of objections to extensive segments of every challenged experts' testimony, characterizing the objected-to testimony as impermissible narrative or unhelpful summaries, excludable corporate intent and state-of-mind testimony, and/or impermissible legal conclusions. *See* Dkt. No. 2889-1 (objections based on Br. #4 cited most often as justification for exclusion). These types of objections are more frequently raised in the context of trial, and for good reason: the context of the testimony and the purpose for which the testimony is offered matters. Nevertheless, I will generally address the objections below.

1. Narrative

JLI argues that significant portions of plaintiffs' experts' opinions are nothing more than impermissible and unhelpful "narration" of the content of defendants' documents or deposition

testimony, their views of the relevant regulatory schemes, and defendants' financial documents and sales information, all of which jurors could understand on their own.

Particular objections to specific experts will be addressed below. I will not exclude expert testimony that helps explain the regulatory background that is relevant to this case or testimony regarding, for example, JLI's marketing and advertising campaigns. The experts appropriately reviewed thousands of pages of documents and extensive data sets and then offered condensed testimony regarding defendants' financial documents and sales information.[22] This testimony may be subject to narrowed and targeted objections at trial but it will not be excluded now.

2. State of Mind

JLI objects to what it characterizes as plaintiffs' experts' opinions about JLI, Altria, and the individual defendants' corporate knowledge and intent in developing and marketing JUUL, as well as their apparent knowledge of and reactions to the problem of youth uptake. It also moves to exclude expert comparison of acts of the defendants and their agents against industry or regulatory "standards of conduct." It argues that the industry standard testimony violates Rule 702 because it is not helpful and not based on actual expertise possessed by many of the experts.

Particular objections will be addressed below. Generally, "state of mind" and "intent" objections are better ruled on at trial: the context of the testimony and the purposes for which it is offered are critical. However, the knowledge of various defendants and witnesses about the topics identified above is likely relevant and admissible if there is a basis in the record for those experts to testify, *e.g.*, from their review of defendants' documents or deposition testimony. Objections to testimony based solely on speculation about intent and motivation may be made at trial and will be sustained where appropriate.[23]

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[22] The ODDs likewise move to exclude expert testimony where plaintiffs' experts' allegedly act as "human highlighters," but then criticize the experts for their failure to address or review evidence the ODDs believe is relevant. *See* ODDs MTE at 26-28. The ODDs motion on those grounds is DENIED consistent with this guidance and subject to objections at trial and cross-examination.

[23] The ODDs' and Founder and Directors' objections to expert testimony about what defendants knew or intended are likewise better determined at trial, depending on the context of and purpose for the expert's testimony. *See* ODDs MTE at 24 n.8, 25 n.9 (identifying opinions by Eissenberg, Grunberg, Halpern-Felsher, Levy, Prochaska, Proctor, Ribisl, Shihadeh, and Winickoff); Monsees MTE at 3-4; Bowen MTE at 3-6.

3. Legal Opinions

JLI moves to exclude numerous portions of plaintiffs' experts' reports where, according to JLI, the experts attempt to reach "ultimate issues of law." It generally points to places in the expert reports where plaintiffs' experts opine that defendants' conduct was false, misleading, deceptive, irresponsible, unreasonable, or reckless. And it attacks opinions that defendants' products were defective, unreasonably dangerous, and failed to meet reasonable consumer expectations.

In the Ninth Circuit, experts are allowed to testify about industry standards even where the testimony "relie[s] in part on [the expert's] understanding of the requirements of . . . law." *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1017 (9th Cir. 2004); *see also United States v. Holmes*, No. 5:18-CR-00258-EJD-1, 2021 WL 2035177, at *4 (N.D. Cal. May 21, 2021) (allowing expert testimony that will "focus will be on whether [a company] adhered to industry standards, not whether [the company] violated applicable regulations. While certain conduct may implicate regulations, the Court anticipates that any confusion or unfair prejudice resulting from testimony about regulatory violations can be mitigated by careful examination and thoughtful language."). That an expert testifies that a defendant violated industry standards or even identified regulations does not mean that the expert is making an impermissible legal conclusion; admissibility depends upon the context of the opinion (when it comes in and what it comes in for) as well as the claims at issue in particular cases.

Generally, plaintiffs should not solicit expert opinions that a defendant violated specific laws or regulations where there is no legal basis for that opinion or where that opinion touches an ultimate issue in a particular case. Experts will, for example, not be allowed to testify that JLI "violated" the MSA when it is undisputed that JLI was not bound by the MSA. The experts in B.B.'s trial should refrain from characterizing JUUL as "defective," "unreasonably dangerous," or using other terms of art under the TPLA that will be ultimately determined by the jury.[24] Specific

[24] The ODDs and Founder and Directors' identical objections to plaintiffs' experts' testimony that they acted unreasonably, controlled JLI, and misled or failed to warn consumers as improper legal conclusions will be handled in the context of each trial. *See* ODDs MTE at 25-26 & fns. 12-16 (objecting to testimony by Eissenberg, Grunberg, Halpern-Felsher, Jackler, Lindblom, Pratkanis, Prochaska, Proctor, Ribisl, Shihadeh, and Winickoff); Monsees' MTE (Dkt. No. 2712-2) at 3;

objections will be addressed and ruled on in the context of each trial.

F. Failure to Act *Daubert*/Brief #5

JLI moves to exclude testimony by numerous experts about what JLI failed to disclose, arguing that testimony is irrelevant, unhelpful, or outside the experts' areas of expertise.

1. Preempted Warnings or Impermissible Legal Conclusions Regarding Nicotine Addiction

JLI argues that plaintiffs' experts cannot offer any opinions on "nicotine addiction" warnings because any such warnings are preempted by the FDA's mandated minimum nicotine warning. As discussed above, the scope of possible preemption hinges directly on the claims at issue in a particular case; for example, the scope and effect of preemption is different for the class claims than it is for B.B.'s product liability claims. *Compare In re JUUL Labs, Inc., Mktg., Sales Pracs., & Prod. Liab. Litig.*, 497 F. Supp. 3d 552, 588 (N.D. Cal. 2020), *with* April 29, 2022 Order [Dkt. No. 3083] at 11-15 (finding product liability failure to warn claims asserted under Tennessee law fall within savings clause and are not expressly or impliedly preempted). I have generally ruled that the maximum potential preemptive effect is limited to labelling claims that would implicate the FDA's mandated minimum nicotine addiction warning.

JLI's motion does not engage in the type of claim-by-claim analysis required to show that any particular experts' failure to warn opinions is preempted and excludable. Therefore, expert opinions will not be excluded wholesale on the basis of preemption. As with the B.B. trial – where the parties have been directed to meet and confer on the scope of what B.B.'s experts may testify regarding failures to warn under Tennessee law – potential objections grounded in the claims at issue will be handled pre-trial on a case-by-case basis.[25]

That case-by-case analysis will also address JLI's concerns over plaintiffs' experts testifying to warnings that could, under those laws, be considered impermissible legal conclusions.

Bowen MTE (Dkt. No. 2714-3) at 3-6.

[25] The parties have also been directed to meet and confer on the scope of any narrow preemption on nicotine addiction labelling claims in light of the FDA's mandated minimum nicotine addiction warning; plaintiffs' position on the issue for B.B.'s trial was unclear.

Generally, expert testimony on adequacy of warnings is a permissible topic for expert input and helpful to the jury. *See, e.g.*, *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 440 (E.D.N.Y. 2011) (allowing expert testimony regarding why labels were false or misleading where "experts reached their conclusions by comparing facts in evidence with the content shown on drug labels and in the warnings, which is a commonly accepted methodology used by experts admitted to testify as to the accuracy of warnings.") (citing *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *12 (E.D. Pa. June 20, 2000)). If JLI has authority under particular laws from jurisdictions in cases being tried within this MDL that experts are not allowed to opine on identified issues related to failure to warn claims, it should present those arguments in limine or through other appropriate mechanisms.

2. Health Warnings

JLI seeks to exclude testimony regarding warnings on other health effects that the FDA considered but did not adopt. I have repeatedly rejected this same conflict preemption argument on the current record. *See* April 29, 2022 Order at 13-14.

JLI also seeks to exclude expert testimony that a warning was "adequate" or "inadequate," arguing those opinions invade the province of the jury. It presents no evidence under Tennessee law that experts cannot opine that warnings were adequate or inadequate. As with nicotine and addiction warnings more generally, whether or not an expert encroaches on the jury's role depends on the state law claims at issue. This is better determined in limine or pretrial.[26]

3. Pre-Launch Research, Different Manufacturing Processes, Quality Control Protocols.

JLI attacks the opinions of plaintiffs' experts about what it should have done pre-launch or on quality control because those experts do not identify any regulatory or legal requirements or applicable standards of care or industry standards that JLI failed to follow in its testing or quality

[26] The only particular non-addiction failure to warn health effects opinions expressly challenged by JLI are Noar's regarding the presence of certain toxins in the JUUL vapor. Failure to Act *Daubert* at 6-7. When and if Noar testifies, the scope of what he may testify to regarding warnings must be tethered to testimony from identified toxicologists supporting his opinions. JLI's qualifications challenges to various experts' opinions on warnings will be addressed below with respect to each expert.

control. Instead, according to JLI, Eissenberg, Prochaska, Casey, Tackett, and Shihadeh opine without basis on what they believed JLI should have done, including: (1) conducted randomized controlled trials on the cessation rate and/or lowest effective nicotine dose for JUUL; (2) performed additional toxicology studies; (3) conducted pharmacokinetic testing on or otherwise determined the switching efficacy of lower nicotine concentration e-liquids; or (4) abided by different manufacturing practices or quality control procedures. JLI's arguments – that these steps were either not required by the FDA (although JLI was "guided" by FDA guidance), were unethical (suggested testing), not conducted by any other e-cigarette manufacturer, or relevant only to tobacco companies but not e-cigarette manufacturers – provide grounds for cross-examination, not exclusion. JLI is free to cross-examine on the lack of regulatory standards and the design choices it made, but its quality control and manufacturing decisions are critical to product defect claims, among others.[27]

II. EXPERT-SPECIFIC CHALLENGES

A. Steve Boyles

Steven B. Boyles is a Member of Five Corners Consulting Group, LLC ("Five Corners"). Five Corners is a forensic accounting and litigation-consulting firm that was retained by plaintiffs to "conduct an analysis on the special dividend distribution provided by JUUL Labs, Inc. to investors and identify the portion of such distribution that pertains to the wrongful acts" alleged by plaintiffs. That analysis relies in part on the damages analysis of plaintiffs' damage expert Hal J. Singer. Boyles Report [Dkt. No. 2687-5] ¶¶ 1, 7.

1. ODDs

The ODDs seek to exclude Boyles' opinions that purport to determine the amount of the Altria investment connected to "wrongdoing." They argue that his opinions are unhelpful because

[27] The two topics JLI focuses on in its quality control and manufacturing section are criticisms of JUUL's "wick and coil" design and manufacture and criticisms that JLI failed to establish a "total particular matter" or "TPM" standard prior to launch. Failure to Act *Daubert* at 15-19. The alleged failure of plaintiffs' experts to point to a standard regarding use of multiple manufacturers or variability in pod performance, their failure to perform a "systemic review" of the wick and coil information JLI provided to the FDA in connection with its PMTA, and their failure to identify a regulation or standard that directly governed TPM in the developing e-cigarette market at the time of JUUL's launch, raise grounds for cross-examination.

they do not fit any viable liability theory (as the disgorgement he establishes is unavailable as a matter of law) and his analysis suffers from significant methodological deficiencies.

Considering liability theories, the ODDs assert that Boyles' attempt to quantify restitutionary disgorgement – the amount received by the ODDs and other JLI investors as a result of JLI's bad acts that led to Altria overvaluing its investment and paying more than it would have in a but-for world – is irrelevant to the "majority" of the claims asserted by plaintiffs in this MDL. The ODDs argue that disgorgement is not an appropriate remedy in the personal injury cases or the government entity cases and is not properly considered restitution under the California Unfair Competition claim or other consumer protection claims.

Boyles' analysis – linked to Singer's analysis of what the class lost (in overpaying for JUUL) and how that impacted the price Altria paid JLI and, therefore, the value received by the ODDs – is tenuous but will not be stricken at this juncture. The relevance or fit of that testimony is better determined in the context of trial and claims being asserted in a particular case, *e.g.*, if the claims allow for restitution or disgorgement as remedies.[28] The methodological attacks the ODDs make against Boyles are DENIED as they do not attack his methodology: they really attack his reliance on Singer (whose merits report has not yet been tested) and his assumptions and ultimate conclusions (*e.g.*, Singer/Boyles ignore that some part of JLI's business was "legitimate," disregard "real world" evidence, and their assumptions if carried to extremes would lead to a negative valuation of JLI). Those are generally grounds for cross-examination, not exclusion.

2. Founder and Directors

Monsees moves to exclude Boyles' testimony regarding the value of Altria's investment to Monsees because no restitution can be due from Monsees as a matter of law and Boyles' estimates are unrealistic and absurd. Monsees MTE [Dkt. No. 2712-2] at 2. Bowen similarly objects, contending that Boyle's testimony on these topics is unhelpful and unreliable. Bowen MTE [Dkt. No. 2714-3] at 2. The motions to exclude Boyles on these grounds are DENIED. The

[28] As of April 15, 2022, Boyles was unlikely to be called by B.B., at least in her case-in-chief, although he was listed on B.B.'s April 1, 2022 witness list. Dkt. Nos. 3040, 3062-5. The ODDs may reraise their relevance arguments concerning Boyles in the context of a trial or proceeding where Boyles is likely to testify.

question of relevance or fit, as with the ODDs, is better determined in the context of a trial where restitution or disgorgement are in play as potential remedies. The methodological attacks are, again, mostly disagreements about Boyles' conclusions. They are appropriate for cross-examination, not exclusion.

B. Dr. Alicia Casey

Dr. Alicia Casey is a pediatric pulmonologist and clinical researcher at Boston Children's Hospital (BCH), with expertise in the care for children with rare interstitial and diffuse lung disease and the pulmonary effects of vaping. JLI Ex. 1, Casey Generic Report [Dkt. No. 2690-4] at 4; *see also* Casey B.B.-specific Report [Dkt. No. 2696-4]. She is the Co-Founder and Co-Director of the BCH Children's Interstitial Lung Disease Program and the founder and director of the BCH Pulmonary Vaping Program overseeing the programs' clinical care and research initiatives. *Id*. That Program involves clinical experts in Pulmonary Medicine, Adolescent Substance Abuse, Toxicology, Pathology and Radiology to coordinate clinical, research, and advocacy efforts for patients with pulmonary symptoms related to vaping. *Id*. at 5. Dr. Casey opines on the pivotal role of JUUL in creating the vaping epidemic, the chemical components of JUUL and its inhalant toxicology concerns, the harmful pulmonary effects from JUUL, the harmful effects associated with the high nicotine content in JUUL, the toxic effect associated with flavorings and stabilizing agents in JUUL and the impact of particulate matter in JUUL on the lungs, and JUUL's lack of warnings regarding these risks. *Id*. at 7-1.

JLI objects to Casey's opinions regarding warnings and labels as outside of her expertise and that there is no "reliable evidence" of the alleged health effects that were not included in JLI's warnings. Br. #5 at 7:5-8:14; Reply Br. #5 6:2-16 (citing Casey Report at 10). Casey does not opine on how JLI should have drafted or conveyed potential warnings, but instead opines that it should have warned consumers about health effects but did not. That testimony is within her area of expertise. DENIED.[29]

[29] Whether sufficient, reliable causative evidence has been adduced to allow testimony about the identified health risks has been deferred.

JLI moves to exclude Casey's testimony on what JLI knew regarding health effects as impermissible intent and state of mind testimony. Br. #4 at 22:10-21; Reply Br. #4 at 21:6-8 (citing Casey Report at 9-10, 14, 16). DENIED, consistent with guidance above.

JLI objects to Casey's opinions on nicotine toxicity and her opinions on its early research as unsupported. Br. #3 at 13:7-14:3; Br. #5 at 12:17-13:14; Reply Br. #3 at 4:8-15:6; Reply Br. #5 at 10:6-15:2 (citing Casey Report at 7-9, 10-14, 23). DENIED, for the reasons identified above.

JLI contends Casey's B.B. specific youth causation opinions are unreliable. Br. #1 at 49:19-51:28; Reply Br. #1 at 37:10-39:2 (citing Casey Report at 8). DENIED.

JLI argues that Casey's opinions that JUUL use can generally cause respiratory issues, impaired brain development, anxiety, and mood and behavior disorders (including causing B.B.'s social and academic declines) should be excluded as lacking in methodology and unreliable. Br. #3 at 15:1-16:8, 18:17-22:27, 23:2-29:13; Reply Br. #3 at 15:9-20:8, 20:22-24:11 (citing Casey Report at 3, 6-8, 10-19, 22-35). DENIED, consistent with above.[30]

C. Dr. John Chandler

Dr. John Chandler is a clinical professor of marketing at the University of Montana, with a master's degree in mathematics and a doctorate degree in statistics, who has worked in analytics and data science for 22 years with a focus on digital marketing. JLI Ex. 3, Dkt. No. 2690-7. He opines that JUUL: seeded its marketing in events that would appeal to youth and that would encourage youth to disseminate product information on social media; co-opted user-generated content on social media to proliferate awareness of its products in markets dominated by youth consumers; employed marketing strategies that succeeded in generating viral marketing spread that foreseeably bled extensively into youth markets; and dominated and continues to dominate vape-related discourse on Twitter as a result of its marketing activities.

JLI contends that Chandler's opinions on consumer perception, reach, and youth causation are excludable as unreliable and lacking in an accepted methodology. Br. #1 at 10:5-16:18, 28:20-

[30] Challenges to opinions regarding seizure, asthma, EVALI, GERD, and other non-addiction health effects have been deferred. Similarly, JLI's challenges to Casey's B.B. specific report and medical monitoring opinions need not be addressed as Casey has not been disclosed as a potential witness in B.B.'s case. *See* Dkt. No. 3062-5.

49:16; Reply Br. #1 at 14:5-10, 34:14-37:7 (citing Chandler Report at 8-9, 12, 22-23, 25-26, 29, 30-34, 41-42, 48, 66, 68-80). Chandler may rely on his extensive relevant experience – along with his review of JLI's own documents and identified research and publications – for his opinions on these topics. That Chandler may have only analyzed Twitter data beginning in 2017 and failed to review early JLI campaigns impacts the weight of his opinions and does not require exclusion. DENIED.

JLI also argues that fit is missing as Chandler analyzes JLI's advertisements under an inapplicable appropriateness standard. Br. #1 at 19:12-20:13; Reply Br. #1 at 16:13-17:7 (citing Chandler Report at 12-24, 64-65, 68-74). This challenge goes to weight and is appropriate for cross-examination, not exclusion. JLI will be free to challenge Chandler on his views regarding "bleed" for advertising "aimed" at adults but that nonetheless is known in the industry to reach youth audiences. DENIED.

JLI argues that Chandler's expertise is limited to marketing analytics and not creative content, and therefore objects to comments about creative content and corporate intent. Br. #4 at 9:21-10:7, 17:1-10 (citing Chandler Report at 3-5, 8). DENIED, consistent with guidance above.

JLI objects to Chandler's impermissible summary of marketing documents and events as impermissible narrative. Br. #4 at 9:21-10:17; Reply Br. #4 at 11:11-23 (citing Chandler Report at 9-15, 23-31, 32-74). DENIED.

JLI objects to Chandler's testimony about what JLI intended with its marketing as impermissible intent and state of mind evidence. Br. #4 at 17:1-10; Reply Br. #4 at 21:9-25 (citing Chandler's Report at 6-9, 11, 13-14, 23, 25, 29-30, 34, 39, 44, 46-48, 50-52, 57-58, 65, 68.) DENIED, consistent with the guidance provided above.

D. Dr. David Cutler

Dr. David Cutler, the Otto Eckstein Professor of Applied Economics at Harvard University, is a public health economist. He also holds appointments at the Kennedy School of Government and the School of Public Health. He has published extensively on the economic and public health impacts of tobacco and regularly analyzes the relationship between addictive goods

and societal harms, including as an expert witness. JLI Ex., 4, Dkt. No. 2690-8. Cutler opines that JUUL and Altria were responsible for the recent increase in youth usage of e-cigarettes. He uses standard economic and econometric methodologies, including utilization of direct and indirect regressions that relied on numerous variables and data to establish these relationships. He concludes from an economic perspective that there is a youth vaping epidemic, that there is no evidence that youth use of e-cigarettes substituted for combustible cigarettes, and that there are both short and long-term costs and harms associated with youth use of e-cigarettes.

JLI argues that Cutler lacks expertise to opine on the "corporate intent" of defendants and moves to exclude limited opinions on that topic. Br. #4 at 17:22-20:24 (citing Cutler Report at 99-100). Cutler can opine based on what defendants knew as long as there is an evidentiary basis to support it. DENIED. Similarly, JLI objects to Cutler's testimony about what JLI knew and intended regarding its marketing and product design as impermissible intent and state of mind testimony. Br. #4 at 20:22-20:24; Reply Br. #4 at 20:13-19. DENIED, consistent with the guidance above.

More significantly, JLI objects to Cutler's opinions on consumer perception and general youth causation for lack of methodology and unreliability. Br. #1 at 10:5-16:18, 28:20-49:16; Reply Br. #1 at 26:21-29:2, 31:6-27, 34:14-37:7 (citing Cutler Report at 12-15, 19-25, 36, 52, 62-67, 68-86, 89-99,103-104, 109-110, 185-200). It specifically targets Cutler's attempts to forecast what youth vaping rates would have been but for JUUL, arguing that Cutler's core market equilibrium assessment is unreliable and his regression analysis inappropriately assumed that explanatory variables would remain static. Not surprisingly, JLI's rebuttal expert (Orzag) disagrees with Cutler. JLI also criticizes Cutler's analyses for only ruling out explanatory variables but not ruling in variables; he failed to identify what variables were significant to support that JLI caused the youth vaping epidemic.

JLI does not dispute that Cutler performed the type of regression analyses that are broadly accepted as admissible in similar cases, and indeed faults plaintiffs' other experts for not performing regression analyses. Marketing *Daubert* at 30-31. Cutler confirmed the results of his regression analyses by citing to literature/research, discovery, and JUUL sales figures. JLI's

objections do not truly go to Cutler's methodology (regression analysis), but to the inputs used and results generated. Those are classic criticisms that go to weight, not admissibility. *Maitland v. Univ. of Minn.*, 155 F.3d 1013, 1017 (8th Cir. 1998) ("a regression analysis does not become inadmissible as evidence simply because it does not include every variable that is quantifiable and may be relevant to the question presented . . . . [I]f a regression analysis omits variables it is for the finder of fact to consider the variables that have been left out of an analysis and the reasons given for the omissions, and then to determine the weight to accord the study's results."). JLI's objections are DENIED.

E. Dr. Minette Drumwright

Dr. Minette (Mimi) Drumwright is the William David Blunk Memorial Professor and a University Distinguished Teaching Professor at the University of Texas at Austin. JLI Ex. 5, Dkt. No. 2690-9. She offers opinions concerning the nature and impact of JUUL's marketing and advertising as well as the corporate codes and standards applicable to the JLI Board of Directors and to Altria in their marketing and advertising decisions.

1. JLI

JLI challenges Drumwright's opinions that discuss the MSA and other inapplicable laws and analyze advertisements under an inapplicable appropriateness standard as lacking in fit. Roadmap at 17-18, Br. #1 at 17:14-19:11, 52:11-54:9; Reply Br. #1 at 14:24-15:7, 15:8-16:12, 39:12-43:6 (citing Drumwright Report at 7-8, 10, 36-43, 80-81, 88-89, 106). Whether the marketing conduct violated norms like those included in the MSA can be explored on cross-examination. Consistent with the guidance above and the Order on the motions in limine, use of term "violated" in context of a non-signatory to MSA or with respect to the FTC Endorsement Guides should be avoided. DENIED.

JLI objects to Drumwright's opinions on youth prevention, corporate responsibility, professional codes, and standards of care as outside of her expertise. Br. #1 at 54:11-57:25; Reply Br. #1 at 3:10-25, 43:9-44:14; Br. #4 at 25:7-26:4 (citing Drumwright Report at 7-8, 22, 29-152). Drumwright has adequately identified her background to discuss standards and professional associations. Opinions regarding youth prevention specifically that are not sufficiently connected

to established codes and standards or that may approach or exceed the boundaries of her expertise may be challenged at trial depending on the scope of Drumwright's testimony. DENIED.

JLI moves to exclude Drumwright's summary of documents and testimony as impermissible and unhelpful fact narrative. Br. #4 at 2:23-28, 11:6-20; Reply Br. #4 at 3:6-7:13 (citing Drumwright Report at 14-23, 52-80). DENIED.

JLI objects to Drumwright's opinions concerning JLI and its Board's violations of codes and standards as impermissible legal conclusions. Br. #4 at 25:7-26:4; Reply Br. #4 at 27:16-28:3 (citing Drumwright Report at 7-8, 29-152). DENIED, consistent with the guidance above. Plaintiffs' experts shall not opine on elements of claims or ultimate conclusions of laws on causes of action at issue in particular cases that are the province of the jury. They may opine about whether conduct fell below standards in the industry as long as that testimony is relevant to the particular claims at issue.

JLI objects to Drumwright's opinions about what JLI intended with its marketing as impermissible intent and state of mind testimony. Br. #4 at 14:9-15:2; Reply Br. #4 at 18:25-19:4 (citing Drumwright Report at 52, 85-86, 90). DENIED, consistent with the guidance above.

JLI objects to Drumwright's assessment of consumer perception and her youth causation opinions as lacking fit and methodology and as unreliable. Br. #1 at 10:5-16:18, 28:20-49:16; Reply Br. #1 at 14:19-21 (citing Drumwright Report at 63, 90, 100). DENIED, as Drumwright's reliance on JLI's own documents and research and publications is sufficient.

Finally, JLI attacks Drumwright's personal opinions regarding youth prevention as unreliable. Br. #1 at 19:1-11, 54:11-57:25; Reply Br. #1 at 44:17-45:12 (citing Drumwright Report at 22, 90, 105). DENIED, subject to objections during trial as appropriate.

2. Altria

Altria argues that Drumwright's sworn deposition testimony confirms that her opinions that Altria's efforts to expand the distribution and sales of JUUL expanded youth access and caused harm to youth, young adults, and consumers generally are based on speculative assumptions. Altria notes that Drumwright admitted performing no empirical "analysis" – such as a regression analysis – to measure the alleged impact and did not review specific Altria data

showing the supposed connection; she instead relied on the general principle that if you increase distribution, you increase sales. Altria contends that Drumwright and the other experts' failures[31] to conduct empirical analysis mean that their opinions are merely *ipse dixit* and that they cannot rely on that general principle to show that Altria harmed youth generally and B.B. specifically. Altria also contends that Drumwright's and the other experts' opinions that Altria caused harm should be excluded because they do not rule out other causes, merely rely on speculation, and do not address the impact of e-commerce or how the relocation of JUUL products to behind counters impacted the sales or youth use.

These objections go to weight, not exclusion. The established general correlation between the provision of services and contemporaneous increase in sales provides a basis for their opinions. That these experts did not perform an empirical analysis of the data does not require their exclusion.[32] Altria may, of course, cross examine Drumwright and the other experts on this issue and present contrary evidence.

3. ODDs

The ODDs seek to exclude the testimony of Drumwright – who opines on codes of conduct

[31] Altria objects and also moves to exclude the statements of Grunberg, Jackler, Pratkanis, Shihadeh, Winickoff, and Prochaska that Altria's conduct contributed to the youth vaping epidemic generally or B.B.'s use of JUUL specifically for the same reasons; their failure to conduct any empirical analysis.

[32] The cases Altria relies on – discussing experts' failures to establish medical causation because the experts failed to account for other explanations of what could have caused plaintiff's illness/disease – are inapposite to the challenged experts' opinions here that Altria's services led to increased sales/availability of JUUL products generally and the youth-favored mint pods in particular. *See, e.g.*, *Sanderson v. Int'l Flavors & Fragrances, Inc.*, 950 F. Supp. 981, 1003 (C.D. Cal. 1996) ("because her experts were utterly unable to tie her injuries to any particular exposure or product, plaintiff's claim that her injuries were caused by her 22 to 32 exposures to IFF's products, rather than her 16,000 exposures to other companies' products, is pure speculation, 'mere possibility' rather than a 'reasonable medical probability.'"); *In re Silicone Gel Breast Implants Prod. Liab. Litig.*, 318 F. Supp. 2d 879, 890 (C.D. Cal. 2004) (looking at "general and specific causation" based on "animal studies, differential diagnosis and epidemiological studies."). As a case relied on by Altria notes, as "expert who relies solely or primarily on his experience 'must explain how that experience leads to the conclusions reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.'" *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Pracs., & Prod. Liab. Litig.*, 978 F. Supp. 2d 1053, 1067 (C.D. Cal. 2013) (quoting Fed.R.Evid. 702). Unlike in Altria's cases, plaintiffs' experts have explained how their experience leads to the conclusions reached, why it is a sufficient basis for the opinion, and how it is reliably applied to the facts.

for corporate boards of directors and corporate conduct – arguing that (i) she is not qualified because her expertise is in marketing, not corporate conduct; (ii) her testimony is irrelevant because "ethics" are not laws; and (iii) her testimony is confusing and prejudicial because she invites the jury to conflate "ethics" and "laws."

Regarding her qualifications, plaintiffs have adequately identified the bases for Drumwright's testimony on the conduct of boards of directors and corporations. That the courses she teaches generally focus on other matters does not make her unqualified to opine on standards of corporate conduct. To the extent that Drumwright espouses opinions based solely on "aspirational" principles – *e.g.*, corporate board directors should be good societal "stewards" and "do no harm" – the ODDs' objections may be sustained depending on the particular context of the claims asserted against the ODDs. These objections are better determined in the context of each trial where the ODDs will be defendants, considering the claims asserted against them and the applicable legal standards.[33]

The ODDs' requests to exclude Drumwright's testimony based on irrelevance and risk of

[33] The cases the ODDs cite support this reasoning. *See, e.g., In re Bard IVC Filters Prod. Liab. Litig*., No. MDL 15-02641-PHX DGC, 2018 WL 495187, at *3 (D. Ariz. Jan. 22, 2018) (rejecting "ethics" expert testimony where the documents relied on "contain ethical and practice guidance for doctors; they say nothing about the legal responsibilities of device manufacturers," recognizing, "[w]hat a reasonably prudent physician would expect may be relevant in a medical malpractice case where the medical standard of care is at issue, but Plaintiffs cite no authority to show that it sets the legal standard for medical device manufacturers under the state tort laws applicable in this MDL proceeding."); *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *9 (E.D. Pa. Feb. 1, 2001 (excluding expert opinion where "expertise and experience in clinical medical ethics are, at best, only marginally relevant to AHP's conduct in the manufacturing and marketing of diet drugs," and "expertise [that was] garnered largely from the study of medical ethical issues in individual patient cases, simply does not qualify him to render opinions concerning the appropriate conduct of pharmaceutical companies in the manufacture and marketing of drugs."); *In re Rezulin Prod. Liab. Litig*., 309 F. Supp. 2d 531, 543 (S.D.N.Y. 2004 (excluding experts' "personal opinions" "regarding ethical standards for reporting or analyzing clinical trial data or conducting clinical trials" because those opinions "articulate nothing save for the principle that research sponsors should be honest. Even if charitably viewed as a 'standard,' the testimony nevertheless is 'so vague as to be unhelpful to a fact-finder.'"). The *Rezulin* court also excluded expert "ethics" testimony because of its "marginal relevance" where the legal questions were "the obligations of a pharmaceutical company in testing, surveying and labeling medications," and those "obligations, not what is ethical, are the central issues in this case." 309 F. Supp. 2d at 544. Whether the ODDs here violated duties owed to particular plaintiffs under different laws or are otherwise liable to particular sets of plaintiffs must be determined on a case-by-case basis.

juror confusion/prejudice are largely DENIED. The differences between ethics, standards, and legal requirements can be explored on cross-examination and are not reasons for exclusion. If necessary, a limiting instruction can be provided, but the appropriateness of a limiting instruction will depend on the context and purpose of the testimony, as well as the particular claims at issue in a particular trial against the ODDs (who are not defendants in the B.B. trial).[34]

F. Dr. Thomas Eissenberg

Dr. Thomas Eissenberg is a Professor of Psychology and the Co-Director of the Center for the Study of Tobacco Products at Virginia Commonwealth University. He has spent decades researching the physiological, subjective, and behavioral effects of novel tobacco products. Eissenberg Report [JLI Ex. 6, Dkt. No. 2690-10] at 4-11. He offers opinions that: (1) JUUL's abuse liability is unreasonably high due to JUUL's high nicotine concentration, additives that promote the delivery of large doses of nicotine, flavors that appeal to non-smokers, and design features that promote concealed use; and (2) although JUUL's design process was and is inadequate, it raised warning signs of JUUL's addiction risks that JLI ignored before bringing the product to market in 2015.

JLI objects to Eissenberg's testimony regarding warnings and labels as outside his area of expertise. Br. #5 at 7:13-8:1 (citing Eissenberg Report at 33, 111, 112, 115). The portions of Eissenberg's Report to which JLI objects describe the history of the presence or absence of warnings and suggests that JLI should have considered unspecified warnings regarding the abuse liability of the product and the amount of nicotine delivered. DENIED. Eissenberg is not offered as an expert on and does not opine on the precise language that should have been used for

[34] For example, violation of industry standards would be relevant testimony to help jurors determine duty of care and foreseeability concepts, as well as the reasonableness of conduct. Those concepts would likely be relevant for negligence, strict products liability, and consumer protection claims. Limiting instructions, as contemplated above and discussed in the order on the B.B. motions in limine, will also provide clarity that MSA and other regulations may not have been binding on JLI, but that does not make their standards irrelevant to this case.

The Founder and Directors' motions to exclude opinions of Drumwright for lack of experience in corporate governance, as usurping the role of the jury, and as prejudicial, are DENIED for the same reasons. Monsees MTE [Dkt. No. 2712-2] at 2; Bowen MTE [Dkt. No. 2714-3] at 1-2.

warnings.

JLI moves to exclude Eissenberg's opinions that JUUL products are defective and unreasonably dangerous as impermissible legal conclusions. Br. #4 at 33:12-20 (citing Eissenberg Report at 6, 37, 38, 60, 62, 63, 66, 83, 89, 138, 139, 146, 147). DENIED, consistent with guidance above.

JLI objects to Eissenberg's opinions on what JLI intended regarding its product design as impermissible intent testimony. Br. #4 at 21:1-15; Reply Br. #4 at 20:19-25 (citing Eissenberg Report at 44, 47, 58, 60, 62, 89, 104, 108, 112, 120, 139,140 142, 146, 147). DENIED, consistent with guidance above.

JLI contends that Eissenberg's opinions that the JUUL design was intended to or did target youth and his other design opinions should be excluded as not based on reliable evidence. Br. #1 at 20:17-22:2, 22:17-22, 25:1-26:23; Reply Br. #1 at 17:13-24:8 (citing Eissenberg Report at 101-102, 106-108, 127-145). Whether or not certain elements would be attractive to adult smokers looking to switch and whether the vapor clouds can be played with are matters for cross-examination, not exclusion. DENIED.

JLI moves to exclude Eissenberg's opinions to the extent he misapplies the TCA standard because he fails to assess JUUL as a switching product, fails to conduct an abuse liability assessment, compares JUUL abuse to cigarette abuse, analyzes addictiveness outside of the TCA framework, and provides an "unreliable" addictiveness opinion based on product misuse. Br. #2 at 3:18-21, 5:13-13:3, 13:10-17:2; Reply Br. #2 at 2:4-11:11 (citing Eissenberg Report in full). DENIED, consistent with guidance above.

JLI contends that Eissenberg's toxicity, quality control and manufacturing, and early research opinions are unsupported. Br. #3 at 13:7-20; Br. #5 at 9:22-17:2; Reply Br. #3 at 4:8-15:6 (citing Eissenberg Report at 16, 37, 60, 62-63, 70-97, 99-100, 108-111, 147). DENIED, as raising grounds for cross-examination, not exclusion.

JLI moves to exclude Eissenberg's "preempted" opinions regarding nicotine addiction warnings. Roadmap at 16:15-17:4; Br. #5 at 3:18-4:7 (citing Eissenberg Report at 33, 111-112,

115). DENIED, consistent with the guidance above.[35]

G. Dr. Sherry Emery

Dr. Sherry Emery is a Senior Fellow in the Public Health Group and Director of the Social Data Collaboratory at NORC at the University of Chicago. JLI Ex. 7, Dkt. No. 2696-9. Emery offers opinions that: (1) JUUL was uniquely appealing to youth, and it quickly became extremely popular among youth; (2) JUUL used promotional strategies that have been shown to appeal to youth and have been banned for over 25 years for cigarette promotion, and ignored safeguards the MSA and the 2009 Family Smoking Prevention and Tobacco Control Act put in place; (3) JUUL unreasonably used viral and other marketing/advertising techniques in a way that attracted youth and young adults to its product; (4) adolescents and young adults are more influenced by marketing than older adults; (5) JUUL strategically used social media strategies that exploited youth susceptibility to marketing and advertising; (6) JUUL-related content was pervasive on social media, becoming a prominent topic in the "Public Communication Environment"; and (7) JUUL's viral marketing caused or substantially contributed to cause the epidemic of JUUL and other e-cigarette use among youth in the United States.

JLI argues that the opinions of Emery regarding the inapposite MSA and other inapplicable laws should be excluded. *See* Roadmap at 17:5-13; Br. #1 at 52:11-54:9; Reply Br. #1 at 39:12-43:6 (citing Emery Report at 7, 11, 19-21, 25, 30-33, 35, 65). Relatedly, it objects to Emery's opinions regarding JLI's actual compliance or non-compliance with the MSA and tobacco laws as impermissible legal conclusions. Br. #4 at 26:5-18 Reply Br. #4 at 27:16-28:3 (citing Emery Report at 7, 11, 19-21, 25, 30-33, 35, 65). The motion to exclude these opinions on these grounds is DENIED, consistent with the guidance above and provided in the Order on the motions in limine.[36] Emery is qualified to discuss the background, intent, and provisions of the MSA. Whether JLI ignored or flouted the safeguards in the MSA and the 2009 Family Smoking

[35] Altria moves to exclude opinions of Eissenberg but did not address him in reply as plaintiffs are no longer offering the opinions Altria challenged. Pls. Omnibus Oppo. at 224 n.101.

[36] It is also denied based on the related arguments made in the Marketing *Daubert* brief and the related reply.

Prevention and Tobacco Control Act can be explored on cross-examination or through defense experts.

JLI objects to Emery's testimony regarding JLI's corporate governance and standards of care as outside of her experience. Br. #4 at 26:5-18 (citing Emery Report at 7, 33). DENIED, except that when Emery testifies in a particular trial the foundation for her opinions – if she testifies as to standards of care – must be established. That JUUL was not operating as a tobacco company does not mean that Emery's tobacco-focused experience is irrelevant or that her testimony is excludable.

JLI moves to exclude Emery's testimony regarding consumer perception, youth appeal, and general youth causation as lacking in methodology and fit and, therefore, unreliable. Br. #1 at 10:5-16:18, 28:20-49:16; Reply Br. #1 at 13:18-23, 29:6-10, 34:14-37:7 (citing Emery Report at 12-17, 19-24, 29, 33-34, 36-39, 41-42, 44, 46-47, 49, 58-60). DENIED. JLI's argument that Emery's opinions must be excluded because they fail to distinguish between correlation and causation – because Emery failed to perform an empirical regression analysis – is misplaced for a social scientist who has sufficient experience and who relies on research, government publications, and defendants' own documents. JLI remains free to cross-examine Emery on the bases for her causation-opinions and the connections she draws between JLI's social media efforts and the spike in youth uptake.

H. Dr. Neil Grunberg

Dr. Neil Grunberg is a Professor of Medical and Clinical Psychology and Professor of Neuroscience at the Uniformed Services University of Health Sciences. He has consulted with the Department of Defense, National Institutes of Health, and the FDA regarding nicotine addiction, tobacco use, and behavior health. Grunberg Generic Report [JLI Exs. 8, Dkt. No. 2690-11] at 1, 4-10. He opines in his generic and B.B.-specific reports on the addictiveness, abuse liability, and attractiveness to youth of JUUL. *See* JLI Exs. 8-9, Dkt. Nos. 2690-11, 2696-11.

1. JLI

JLI argues that the opinions of Grunberg regarding the inapposite MSA and other inapplicable laws should be excluded because they fail to apply the correct standards. Br. #1 at

52:11-54:9; Br. #2 at 3:18-21, 5:22-13:3; Reply Br. #2 at 2:4-4:13, 4:15-9:18 (citing Grunberg Report at "in full"). DENIED, consistent with the guidance provided above.

JLI challenges opinions of Grunberg based on lack of fit or lack of methodology, contending that he lacks a reliable assessment of consumer perceptions of toxicity or addictiveness in JLI's advertisements. Br. #1 at 9:4-24, 10:5-16:18; Reply Br. #1 at 9:21-10:12 (citing Grunberg Report at 36, 109-21). Grunberg's opinions concerning the impact of marketing are more centrally focused on consumer behavior and nicotine use; they fall within his expertise and prior research (as a clinical psychologist with extensive experience with behavior health and tobacco products in particular). Relatedly, JLI argues that Grunberg has no reliable evidence or provides unsupported opinions about various design features, including that JUUL's design was intended to or did target youth. Br. #1 at 21:3-16, 22:23-23:6, 25:1-26:23; Reply Br. #1 at 17:13-24:8 (citing Grunberg Report at 104-25). His opinions – considering not just the marketing imagery but also product design, flavors, and other factors – are reasonably based on his experience as well as review of JLI-specific evidence and broader research. JLI's position that these features were incorporated to attract adult users may be explored with Grunberg on cross-examination. It does not require exclusion of Grunberg's supported opinions. DENIED.

JLI argues that Grunberg's opinions on youth causation should be excluded as lacking a methodology and unreliable. Br. #1 at 28:20-49:16, 49:19-51:28; Reply Br. #1 at 30:1-3, 37:10-39:2 (citing Grunberg Report at 3, 146). DENIED.

JLI challenges Grunberg's abuse liability and toxicity conclusions as unsupported or based on product misuse. Br. #2 at 13:10-17:2; Reply Br. #2 at 9:20-11:11; Br. #3 at 14:10-22, 15:15-22; Reply Br. #3 at 4:8-15:6 (citing Grunberg Report at 15-18, 138-42). DENIED for the reasons addressed above.

JLI moves to exclude Grunberg's general injury causation conclusions for lacking methodology and unreliability. DENIED, as explained above, with respect to the injures left in play for B.B.: impaired brain development, anxiety, and mood and behavior disorders. Br.#3 at 22:2-27; Reply Br. #3 at 15:9-20:8 (citing Grunberg Reports at 14, Appx. 1 ¶ 31).

JLI objects to Grunberg's opinions on marketing, engineering, product development,

corporate intent, and consumer and youth behavior as outside his expertise. Br.#4 at 11:20-25, 19:1-3; Reply Br. #1 at 3:10-25 (citing Grunberg Report at 38-41, 43, 48, 51, 54, 59-60, 68, 73, 90-91, 96-97, 102, 104-127, 128, 136-39, 104-27). DENIED, generally, in light of his expertise. To the extent that at trial Grunberg testifies about topics that approach the limits of his extensive expertise and research on tobacco use, JLI may make more targeted objections.

JLI also moves to exclude 20 pages of Grunberg's Report that narrate plaintiffs' theory on JUUL's engineering, product development, and marketing because Grunberg simply summarizes JLI's documents and deposition testimony. Br. #4 at 11:20-25; Reply Br. #4 at 12:17-14:7 (citing Grunberg Report at 104-127). DENIED.

JLI objects to Grunberg's opinions regarding what JLI intended with its marketing, product design, and how those impacted consumer behavior and youth use as impermissible intent and state of mind testimony. Br. #4 at 18:24-19:17; Reply Br. #4 at 20:2-8 (citing Grunberg Report at 2-3, 17, 25, 28, 31-36, 38-41, 43, 48, 51, 54, 59-60, 68, 73, 90-91, 96-97, 102, 106-09, 115, 118, 120, 125-26, 128, 136-39, 141-42. DENIED, consistent with guidance provided above.

Finally, JLI objects to Grunberg's testimony regarding nicotine addiction warnings as preempted and therefore lacking fit. Br. #5 at 3:18-4:7 (citing Grunberg Report at 36, 110). DENIED. The boundaries and limits of expert testimony regarding the lack of disclosures and failure to warn will be refined for each trial in the MDL depending on the claims alleged.

2. Altria

Altria argues that there is no basis for Grunberg's opinion that Altria facilitated JUUL sales because, like Drumwright, Grunberg did not perform an empirical study. As with Drumwright, this goes to weight, not admissibility. Altria separately challenges Grunberg's qualification as a psychology professor to opine on marketing, supply chain management, "or any other subject that would render [him] capable of determining whether the Altria Defendants' conduct caused an increase in JUUL sales or use by underaged used, including B.B." Altria MTE at 11. Grunberg's training in social psychology and experience researching youth addiction to tobacco qualifies him to discuss marketing specifically and Altria's conduct more generally in terms of the services Altria provided JLI. Altria may object to particular opinions of Grunberg as

reaching the limit of his expertise (or made without adequate foundation) at trial.

3. ODDs

The ODDs say that Grunberg is not qualified to give opinions regarding the ODDs' control over JLI's Board of Directors, the unusually involved role of the ODDs on JLI's Board, and, more generally, concerning what the ODDs should have or should not have done as corporate governance. ODDs MTE at 22-24 & n. 6. DENIED. This objection is better determined in the context of what Grunberg actually testifies about at trial. For example, testimony about the ODDs' activities and roles based on review of JLI's documents would generally be allowed, but testimony that compares the ODDs' acts to other directors on other boards would need to have an adequate foundation.[37]

I. Dr. Bonnie Halpern-Felsher

Bonnie Halpern-Felsher is a Professor of Pediatrics in the Division of Adolescent Medicine, Department of Pediatrics, at Stanford University's School of Medicine and a Professor in the Department of Epidemiology and Population Health and in the Department of Psychiatry, at Stanford University. Halpern-Felsher Report (JLI Ex. 10, Dkt. No. 2696-12).

Halpern-Felsher opines that: (1) JLI acted unreasonably in that it failed to live up to its responsibility to protect adolescents and young adults from its nicotine product; (2) youth and young adults are more susceptible to the effects of nicotine and its addictive properties; (3) JUUL's product features made it unreasonably dangerous and attractive to adolescents and young adults; (4) JUUL branding, marketing/advertising and sales were unreasonable in that they were unnecessarily attractive to adolescents and young adults and JLI was or should have been aware of this attraction; (5) JLI did not adequately inform in its advertising, marketing materials, or packaging of the potential dangers of its product nor about the unique risks it presented to adolescents and young adults; (6) JLI caused or substantially contributed to cause a youth vaping

[37] The ODDs' and the Founder and Director Defendants' identical objections to Grunberg and the other experts' opinions on these same subjects are likewise DENIED, as they are better determined in the context of trial. ODDs MTD at 23 n. 6 (objecting to opinions by Eissenberg, Halpern-Felsher, Jackler, Levy, Lindblom, Pratkanis, Prochaska, Proctor, Ribisl, and Winickoff); Monsees MTE at 3; Bowen MTE at 4.

epidemic and increased youth nicotine addiction; (7) JLI did not act reasonably in failing to have adequate youth prevention measures or education programs in place; (8) JLI's Board of Directors knew about the propensity for adolescents and young adults to be attracted to the product and about youth use of the product post-launch, but prioritized sales over youth prevention; (9) Altria's actions surrounding its partnership with JLI were unreasonable, grew the nicotine market and perpetuated keeping mint on the market; and (10) schools should adopt various measures for e-cigarette prevention going forward.

1. JLI

JLI seeks to exclude Halpern-Felsher's allegedly inappropriate legal conclusions regarding health effects warnings and the allegedly inapposite MSA or other inapplicable laws. *See* Roadmap at 16:15-24, 17:5-13; Br. #1 at 52:11-54:9; Reply Br. #1 at 39:12-43:6; Br. #4 at 30:7-20; Reply Br. #4 at 28:4-19; Br. #5 at 7:5-12 (citing Halpern-Felsher Report at 13-15, 56, 63-64, 79, 92-93, 107, 147-151, 154-157, 220-224, 251-252, 259, 261). The motion to exclude these opinions on these grounds is DENIED, consistent with the guidance provided above and in the Order on B.B.'s motions in limine. Halpern-Felsher may opine on the lack of any warnings or disclosures, ambiguity of JUUL's packaging statements (including "5% strength"), the placement of disclosures on JUUL packaging, and inadequate disclosures. What Halpern-Felsher (or other experts) may testify about regarding nicotine addiction warnings on packaging is subject to the ongoing meet and confer process required by the Court's rulings on the parties motions in limine.

Halpern-Felsher is likewise qualified to discuss the background, intent, and provisions of the MSA and federal regulation of tobacco products and/or products containing nicotine, as well as youth prevention. Br. #1 at 54:11-57:25; Reply Br. #1 at 3:10-25, 43:9-44:14, 44:17-45:12 (citing Halpern-Felsher Report at 110-115, 220-283, 293-300).

JLI objects to Halpern-Felsher's opinions concerning corporate intent as outside her area of expertise. Br. #4 at 15:3-25 (citing Halpern-Felsher Report at 79, 96, 136, 208, 283, 289-290). DENIED, subject to establishing the basis for her opinions at trial.

The objections to Halpern-Felsher concerning allegedly impermissible state of mind and intent testimony regarding what JLI intended regarding marketing are DENIED, consistent with

the guidance above. Br. #4 at 15:3-25; Reply Br. #4 at 19:4-7 (citing Halpern-Felsher Report at 12, 13, 18-19, 34, 42, 50, 56, 62-64, 79, 89, 94, 96-97, 110-113, 121, 135-137, 203, 208, 211-215, 220-221, 224, 243, 252, 262, 265, 267, 272, 282-283, 289-90).

JLI also objects that Halpern-Felsher's opinions on consumer perception and youth causation lack methodology and are unreliable. Br. #1 at 10:5-16:18, 28:20-49:16; Reply Br. #1 at 26:21-29:2, 30:3-6 (citing Halpern-Felsher Report at 65-66, 71-78, 106-110, 119-120, 124, 128-132, 135, 140-141, 161-166, 169-173, 177-190, 244-47, 249). DENIED. Halpern-Felsher has adequately identified the bases for those opinions and may testify concerning how defendants caused or contributed to the youth vaping epidemic.

The objections to Halpern-Felsher's testimony regarding toxicity and health effects as unsupported and unreliable are DENIED, for the reasons identified above. Br. #3 at 13:16-26; Reply Br. #3 at 4:8-15:6; Br. #5 at 7:5-12; Reply Br. #5 at 6:2-16 (citing Halpern-Felsher Report at 23-26, 29-32, 161).

2. ODDs

The ODDs object to Halpern-Felsher's attempt to connect the ODDs to "Big Tobacco" by noting the Pritzker family's ties to the tobacco industry as irrelevant and unduly prejudicial. They also move to exclude her testimony regarding the MSA as unduly confusing. Limited testimony regarding the MSA will be allowed consistent with the guidance above and in the Order on the B.B. motions in limine. Halpern-Felsher should not testify concerning the Pritzker family's "long-standing" relationship with the tobacco industry if her testimony is based solely on the activity identified in the ODDs' motion. ODDs MTE at 28.

J. Dr. Robert Jackler

Dr. Robert K. Jackler is a surgeon, professor, and former Chair of Otolaryngology-Head and Neck Surgery at Stanford University's School of Medicine. He is also the founder of the Stanford Tobacco Research Collaborative and the group Stanford Research into the Impact of Tobacco Advertising (SRITA) and has studied tobacco industry marketing for more than 15 years. JLI Ex. 11A (Jackler Report, Dkt. No. 2691-1). Jackler opines that the defendants' branding, marketing, and advertising were unreasonably attractive to youth, were misleading and deceptive,

and did not adequately warn about the risks associated with use of the product. He also opines that defendants knew or should have known that their marketing, branding, and advertising had an unreasonable likelihood of attracting youth yet failed to take appropriate action, and that their conduct substantially contributed to the youth vaping epidemic.

1. JLI

JLI contends that Jackler is unqualified to opine on marketing and youth prevention. Br. #1 at 54:11-57:25, Br. #4 at 8:21-9:19; Reply Br. #1 at 3:10-25, 43:9-44:14 (citing essentially the whole Jackler Report). It ignores that he is the founder of the Stanford Tobacco Research Collaborative and SRITA and has studied, published on, and testified repeatedly about tobacco industry marketing over the past 15 years. Defendants do not dispute that Jackler has authored peer-reviewed studies and academic papers on not only the tobacco industry but also JUUL. Jackler is broadly qualified to opine on marketing as well as youth prevention. DENIED.

JLI objects to Jackler's subjective opinions about JLI's advertising practices – consumer perception in general, consumer perception about toxicity and addictiveness in particular, whether JUUL's design was intended to or did target youth, youth causation, and youth prevention – as methodologically unsound and unreliable. Br. #1 at 7:15-9:3,10:5-16:18, 23:7-15, 28:20-49:26, 54:11-57:25; Reply Br. #1 at 8:6-9:20, 14:11-19, 17:13-24:8; 26:21-29:2, 34:14-37:7, 44:17-45:12 (citing Jackler Reports at 19, 51-52, 56, 58-60, 101-107, 111-12, 122-25, 129, 134-36, 167, 183-84, 186-89, 192, 202-03, 208-09, 217, 221-22, 228-29, 242, 244, 260-275, 279-286, 288-90, 294, 346-51, 357-64, 371-79, 381-87, 420-21). These objections – that go essentially to the whole of Jackler's testimony – are DENIED. Jackler identifies his experience as well as the research (both his own and others) that provides the foundation for his opinions on health effects warnings and his comparisons between cigarette marketing and JUUL's marketing, and explains why he makes those comparisons.

JLI objects to Jackler's impermissible narrative, chronicling the marketing campaigns and tactics used by JLI. Br. #4 at 8:21-9:19; Reply Br. #4 at 10:15-11:9 (citing the whole Jackler Report). DENIED.

JLI objects to Jackler's opinions about what it intended with its marketing as

impermissible intent and state of mind testimony. Br. #4 at 15:26-16:10; Reply Br. #4 at 19:8-11 (citing Jackler Report at 15-19, 22, 27, 32, 36, 48, 67, 81, 112-120, 176-77, 195, 270, 275, 284-285, 331, 352-354, 360, 361, 361, 367, 371-378). DENIED, consistent with the guidance provided above.

JLI moves to exclude Jackler's allegedly inappropriate legal conclusions regarding regulatory requirements and health effects warnings, whether JUUL was sold "without authorization," that JUUL "exploited regulatory loopholes," that JLI's practices were false or misleading and deceptive or unreasonable, that JLI's failure to warn caused youth use, and the inapposite MSA or other inapplicable laws. Roadmap at 16:15-24, 17:5-13; Br. #1 at 52:11-54:9; Reply Br. #1 at 39:12-43:6; Br. #4 at 30:20-31:13; Br. #5 at 1:27-4:22, 7:5-12 (citing Jackler Report at 14-15, 17, 20, 126, 179, 212, 336-346, 352-354, 374-75, 377, 379). The motions to exclude on these grounds are DENIED, consistent with the guidance above and in the Order on the B.B. motions in limine. Jackler may opine on the lack of warnings or disclosures, the ambiguity of JUUL's packaging statements, the placement of disclosures on JUUL packaging, and the inadequate disclosures in advertisements. He may not offer opinions on the adequacy of JUUL's FDA-mandated minimum warning or falsely imply that federal regulations or the MSA required JLI to make specific additional disclosures in specific ways.[38]

2. Altria

Altria argues that there is no basis for Jackler's opinion that Altria's actions ultimately put more JUUL product, including mint pods, in stores because he too conducted no empirical study or other attempt to actually quantify that impact. As explained above, this objection goes to weight, not admissibility.

Altria separately challenges Jackler's qualification as a "trained surgeon" to opine on marketing, supply chain management "or any other subject that would render [him] capable of

[38] The parties are meeting and conferring on a number of limiting instructions for the B.B. trial. Plaintiffs are required to identify the specific warnings they will contend were required under Tennessee law but were missing in marketing or on packaging. The exact boundaries of what plaintiffs' experts will be allowed to testify to regarding adequacy of disclosures and failures to warn will be further refined in the context of each trial.

determining whether the Altria Defendants' conduct caused an increase in JUUL sales or use by underaged used, including B.B." Altria MTE at 11. DENIED. That objection wholly ignores Jackler's extensive experience in analyzing tobacco advertising and marketing efforts, described above.

3. Founder and Directors

Monsees and Bowen object to the opinions of Jackler that the founders "falsely portrayed themselves" as idealistic entrepreneurs who acted with hypocrisy, as derisive and prejudicial characterizations. Monsees MTE at 4; Bowen's MTE at 4. Plaintiffs do not address these objections in their opposition. They shall caution Jackler to refrain from hyperbolic and potentially unduly prejudicial characterizations of any of the defendants.

K. Robert Johnson

Robert W. Johnson, who has 40 years of experience in financial and economic analysis, evaluated the financial condition of defendants for purposes of satisfying any potential punitive damage award. Johnson Expert Report [Dkt. No. 2687-6].[39] The ODDs seek to exclude him because he merely restates ODD deposition testimony that is unhelpful and unnecessary, his testimony is unreliable in that he failed to conduct independent analysis concerning the current net worth of the ODDs, and his opinions do not fit the undisputed facts because he attributes dividends paid to corporate interests associated with or controlled by the ODDs to the individual ODDs.

The ODDs' motion is DENIED. Expert testimony is useful, given the various entities through which the ODDs operated or received dividends. His analysis of the dividend chart and the objections to his conclusions and alleged misapplication of the legal standards for punitive damages go to weight, not admissibility.[40]

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[39] Johnson is unlikely to testify as B.B.'s trial and some of his opinions are subject to a possible stipulation between the parties. Dkt. No. 3062-5.

[40] The Founder and Directors also move to exclude Johnson on the same grounds, arguing that his testimony is unhelpful as it relies solely on deposition testimony and fails to quantify the Founder and Directors' current wealth. Monsees MTE at 2; Bowen MTE at 2. Those motions are DENIED for the same reasons.

L. Dr. Steven H. Kelder

Steven H. Kelder, PhD, MPH is a professor of epidemiology, health promotion, and behavioral science. Kelder holds a PhD in Behavioral Epidemiology, a Master of Public Health in Community Health Education, and a Bachelor of Science degree in Marketing and Economics. JLI Ex. 12, Kelder Report at 1 [Dkt. No. 2699-1]. He served as one of four Senior Scientific Editors for the 2016 Surgeon General Report, E-Cigarette Use Among Youth and Young Adults. He developed an e-cigarette use and JUUL use prevention program, CATCH My Breath, which has been shown through peer-reviewed published research to be effective. JLI Ex. 12, Kelder Report at 6-13. He provided a generic expert report on the nature of the equitable remedy of abatement, identifying strategies that "should be implemented from a prevention perspective at the community level, including in counties, cities, and school districts." JLI Ex. 12, Kelder Report at 15.

JLI objects to Kelder's opinions to the extent that he applies the MSA and/or other inapplicable laws or regulations. Br. #1 at 52:11-54:9; Reply Br. #1 at 39:12-43:6 (citing Kelder Report at 111-12). DENIED, consistent with the guidance provided above.[41]

M. Dr. Sharon Levy

Dr. Sharon Levy is a pediatrician board certified in Developmental Behavioral Pediatrics and Addiction Medicine, and an Associate Professor of Pediatrics at Harvard Medical School. She opines in her generic and B.B.-specific reports (JLI Exs. 13-14, Dkt. Nos. 2699-2, 2699-3) regarding the addictive properties of JUUL and its impact on youth in general and B.B. in particular.

JLI contends that Levy lacks expertise to opine on JLI's marketing and its impact on B.B. specifically or others more generally and lacks expertise to opine on corporate governance. Br. #4 at 11:25-12:3, 18:5-23 (citing Levy Report at 8, 12, 23, 25-27, 33-37, 46-48). DENIED.

JLI moves to exclude Levy's testimony as an impermissible narration. Br. #4 at 11:20-12:3; Reply Br. #4 at 12:17-14:7 (citing Levy Report at 12, 33, 37, 46-49). DENIED.

[41] JLI's objections to Kelder's abatement opinions will be separately addressed in the deferred *Daubert* challenges to the abatement experts.

JLI contends that Levy's opinions on quality control and manufacturing opinion are unsupported. Br. #5 at 15:7-16:23 (citing Levy Report at 27). DENIED.

JLI objects to testimony regarding what it intended with its marketing and product design as impermissible state of mind testimony. Br. #4 at 18:5-23; Reply Br. #4 at 19:25-20:2 (citing Levy Report at 8, 23, 25-27, 34, 36, 46, 48-49). DENIED.

JLI contends that Levy's opinions about consumer perception of JUUL advertisements and that JUUL's design was intended to and did target youth should be excluded as not based on reliable evidence. Br. #1 at 10:5-16:18, 23:16-24:2; Reply Br. #1 at 17:13-24:8 (citing Levy Report at 12, 33-38, 46-48). DENIED.

JLI moves to exclude Levy's general youth causation opinions, as well as her general causation opinions (regarding impaired brain development, anxiety, and mood and behavior disorders) for lack of methodology and as unreliable. Br. #1 at 28:20-49:16; Reply Br. #1 at 29:11-13; Br. #3 at 22:2-27; Reply Br. #3 at 15:9-20:8 (citing Levy Report at 8, 33-37, 38-39, 46, 49). Levy relies on identified research studies to support her opinions in addition to anecdotal evidence from her clinical practice.[42] DENIED.

N. Eric Lindblom

Eric Lindblom has experience in analyzing the regulatory and public health scheme regarding tobacco products and is a Senior Scholar at Georgetown Law's O'Neill Institute for National & Global Health Law, where he previously served as the Director for Tobacco Control and Food & Drug Law. JLI Ex. 15 (Lindblom Report, Dkt. No. 2699-4). Lindblom discusses the regulatory framework that existed when JLI designed, developed, marketed, and sold its e-cigarettes, including tobacco control laws and regulations, common law standards for manufacturers, tobacco control court rulings and settlement agreements, and research-based tobacco control findings and expert recommendations, the consideration of which (according to plaintiffs) established the standards for e-cigarette manufacturers. He opines that JLI failed to

[42] Challenges to opinions regarding seizure, asthma, EVALI, GERD, and "other" lung conditions have been deferred. Similarly, JLI's challenges to Levy's B.B. specific report and medical monitoring opinions need not be addressed, as Levy has not been disclosed as a potential witness in B.B.'s case. *See* Dkt. No. 3062-5.

meet these standards.

JLI moves to exclude Lindblom's opinions on the inapposite MSA or other inapplicable laws. *See* Roadmap at 18:1-11, 19:9-25; Br. #1 at 52:-11-54:9; Reply Br. #1 at 39:12-43:6 (citing Lindblom Report at 7, 31-32). DENIED. Lindblom is qualified to discuss the background, intent, and provisions of the MSA and federal regulation of tobacco products and/or products containing nicotine.

JLI objects to Lindblom's opinions regarding JLI's marketing and defendants' corporate intent on the grounds that he lacks expertise. *See* Br. #4 at 12:10-19, 20:6-16 (citing Lindblom Report at 54-57, 69-85). It similarly objects to his opinions concerning its beliefs regarding product design and marketing as impermissible intent and state of mind testimony. Br. #4 at 20:6-16 (citing Lindblom Report at 54-57, 69-85). DENIED, consistent with the guidance above.

JLI moves to exclude Lindblom's opinion that it failed to meet federal requirements and laws (implemented by the FDA and under the TCA) when it designed and marketed JUUL, as well as his testimony that JLI failed to meet various standards as impermissible legal conclusions. *See* Br. #4 at 26:20-29:9; Reply Br. #4 at 29:10-30:20 (citing Lindblom Report at 10-54, 58-98). JLI's broad request to exclude the vast majority of Lindblom's opinions is DENIED. Lindblom may testify about these topics, in part to rebut defendants' expected testimony that they were guided by the TCA and FDA regulations, as long as that testimony follows the guidance given above and in the Order on the B.B. motions in limine, and consistent with the contemplated limiting instructions.

JLI seeks to exclude part of Lindblom's testimony regarding the chronology of JLI's marketing and product development as impermissible fact narration. *See* Br. #4 at 12:10-19; Reply Br. #4 at 12:17-14:7 (citing Lindblom Report at 27-31, 54-58, 69-81). DENIED.

Finally, JLI objects to Lindblom's "preempted" opinion regarding nicotine warnings and the health effects that were not included in other warnings, based on preemption and lack of reliable evidence. Br. #5 at 1:27-4:22, 7:5-12; Reply Br. #5 at 6:2-16 (citing Lindblom's Report at 78, 80). DENIED.

O. Dr. Seth Noar

Dr. Seth Noar is the James Howard and Hallie McLean Parker Distinguished Professor in the Hussman School of Journalism and Media at the University of North Carolina (UNC) and has studied, researched, and published in the field of health communications, including tobacco prevention and control, recently focusing on studying communication with youth about the risks of e-cigarettes. JLI Ex. 16, Dkt. No. 2699-5. He opines regarding the processes used by JLI to communicate to youth about product risks, including the best practices for health warnings and the inadequacy of JUUL's warnings, how JLI failed to follow best practices for warnings, and the consequence of such failures that led to misperceptions by youth about JUUL's health risks.

JLI objects to Noar's opinions regarding the role of advertising, social media, and product design in youth use as well as the scope of the FDA's authority as matters outside his area of expertise. *See* Br. #5 at 8:15-9:7; Reply Br. #5 at 8:17-10:3 (citing Noar Report at 7.1, 7.2, 7.2.3.3, 7.3, 8.1, 8.1.3). Given Noar's extensive background in communications strategy and messaging, particularly in the public health and youth tobacco prevention fields, this objection is DENIED.

JLI moves to exclude Noar's opinions regarding requirements for health effects warning as impermissible legal conclusions and contends that his opinions regarding nicotine addiction warnings are preempted. Roadmap at 16:15-24; Br. #5 at 2:9-3:17, 4:26-6:12, 6:17-7:4, 9:8-21; Reply Br. #5 at 2:17-5:25, 8:17-10:3 (citing Noar Report at 8.1.6, 8.2, 8.3.1.4, 8.3.2, 8.5.2, 8.5.2.1, 8.5.2.5, 9.1.2, 9.2.1, 9.2.3, 9.2.3.15, 9.2.3.17). DENIED, consistent with above.

JLI contends that Noar cites no reliable evidence that JUUL design was intended to or did target youth. Br. #1 at 22:3-9; Reply Br. #1 at 17:13-24:8 (citing Noar Report at 24). DENIED. Whether JUUL's design elements were also attractive and important to switch adults can be explored on cross-examination.

JLI seeks to exclude Noar's opinions regarding general youth causation opinions for a lack of methodology and as unreliable. Br. #1 at 28:20-49:16; Reply Br. #1 at 29:17-20 (citing Noar Report at Ex. 16 p. 43). DENIED.

JLI objects to Noar's opinions on health effects that were not included in warnings as not

based on reliable evidence. Reply Br. #5 at 6:2-16 (citing Noar Report at 8.5.2.5, 9.2.1, 9.2.3, 9.2.3.15, 9.2.3.17). DENIED.

P. Dr. Anthony Pratkanis

Dr. Anthony Pratkanis is an experimental social psychologist and Emeritus Professor of Psychology at the University of California-Santa Cruz whose primary area of research is social influence and belief formation, including mass communications, deceptive advertising, sales practices, and economic fraud. JLI Ex. 17, Dkt. No. 2699-6. He opines on JUUL's "unique selling proposition (USP)," which is a "tech lifestyle product that satisfies," and that JUUL caused an epidemic of youth nicotine addiction.

1. JLI

JLI argues that the opinions of Pratkanis regarding the inapposite MSA and other inapplicable laws should be excluded. Br. #1 at 52:-11-54:9; Reply Br. #1 at 39:12-43:6 (citing Pratkanis Report at 6). DENIED for the reasons explained above.

Similarly, JLI moves to exclude Pratkanis's inappropriate legal conclusions regarding requirements of health effects warnings. *See* Roadmap at 16:15-24; Br. #5 at 7:5-12 (citing Pratkanis Report at 55-59). It also objects to Pratkanis's testimony regarding the "preempted" nicotine warnings and the health effects that were not included in other warnings, based on preemption and lack of reliable evidence. Br. #5 at 4:8-22, 7:5-12; Reply Br. #5 at 6:2-16 (citing Pratkanis Report at 6, 11, 110). The boundaries of expert testimony regarding disclosures and failure to warn need to be tailored for each case depending on the claims at issue and the applicable preemption rulings. Those boundaries are being refined for B.B.'s case per my rulings and Order on the B.B. motions in limine.

JLI objects to Pratkanis's opinion on the consumer perceptions of toxicity or addictiveness and consumer perception of JUUL advertisements, asserting that he did not apply an appropriate methodology and the opinions are unreliable. *See* Br. #1 at 6:15-7:14, 10:1-16:18 (citing Pratkanis Report at 7, 11, 23-54). In particular, it challenges Pratkanis's opinions regarding JUUL's consistent "unique selling proposition (USP)" that is a "tech lifestyle product that satisfies." It contends that Pratkanis has misapplied the concept of a USP based on nothing more than review

of JLI documents and historical advertisements to "reverse engineer" the USP Pratkanis wanted to reach. However, Pratkanis employed an accepted method of distilling the central message of JLI's marketing materials. At trial, JLI will be free to offer evidence that actual consumers had a different understanding of its USP, or that changes to JLI's advertisements over time precluded a consistent USP, or that consumers took away a wholly different message from JLI's actual marketing campaigns to show that consumers would not have been misled by JLI's marketing or would have found omitted material regarding health impacts immaterial. Those are matters for cross-examination, not exclusion.

JLI contends that Pratkanis's youth causation opinions likewise lack methodology and are unreliable. Br. #1 at 28:20-49:16; Reply Br. #1 at 26:21-29:2, 32:1-33:12 (citing Pratkanis Report at 60-69, 102-108). Its main objection to his testimony on causation is his use of the Bradford Hill factors to assess the impact of JLI's marketing of JUUL and as support for his opinion that JLI caused the youth vaping epidemic.[43] JLI and Pratkanis agree that they are unaware of anyone using those factors to assess causation or impact in a marketing case and that Pratkanis has never performed peer reviewed work analyzing the Bradford Hill factors in the marketing context. In addition to the novelty of his Bradford Hill analysis, JLI characterizes Pratkanis's conclusions regarding JLI's marketing causing youth use as based only on correlation and not causal impact and on unjustified or incorrect assumptions (*e.g.*, that rising sales were evidence of youth causation of JLI's marketing and that JLI's marketing was consistent between 2015 and 2019), and that it fails to rule out or sufficiently address alternate causes in any serious way.

How or how well the Bradford Hill factors map onto causation opinions in marketing cases appears to be a novel question. The essential analysis Pratkanis performed through the lens of the

[43] Typically applied in medical causation cases, once epidemiologists "have concluded from the studies that there is an association between an agent and an outcome, they often assess causation through a framework called the 'Bradford Hill criteria,' named for Sir Austin Bradford Hill, who wrote a 1965 article that articulated nine 'viewpoints' now generally accepted to be relevant to assessing causation. [] Broadly, these factors are: (1) the strength of the association; (2) consistency; (3) specificity; (4) temporality; (5) biological gradient or dose response; (6) biological plausibility; (7) coherence with other scientific knowledge; (8) experimental evidence; and (9) analogy." *In re Viagra (Sildenafil Citrate) & Cialis (Tadalafil) Prod. Liab. Litig.*, 424 F. Supp. 3d 781, 794 (N.D. Cal. 2020) (citing *In re Roundup Prod. Liab. Litig.*, 390 F. Supp. 3d 1102, 1116 (N.D. Cal. 2018)).

Bradford Hill factors, however, was based on published research, JLI's own internal documents (and those of outside marketers hired by JLI), and government publications. His consideration of factors associated with the Bradford Hill analysis does not appear necessary to sustain his opinions that JLI's marketing, including the channels it used (involving the use of influencers and social media more generally as well as prominent retail space to drive sales) caused extensive youth use of JUUL. *See, e.g.*, Pratkanis Report at 63-66 (discussing use of "diffusion of innovation," "hierarchy of effects," and "product trial" models and consideration of principles of experimental research and alternate causes), 67-69 (noting Bradford Hill factors provide a method to "gain an increased confidence in the causal relationship between two variables" and applying those factors); 69-102 (beyond Bradford Hill analysis, conducting a "more detailed analysis of how that epidemic happened," looking at: "(a) how JUUL's marketing communications diffused through social media and other media as well as into everyday life; (b) how JLI's marketing placed JUUL on retail shelf space; and (c) how JUUL came to own the cool kid's mind and how those cool kids became the shelf space and evangelicals for the marketing for JUUL"), 102-108 (ruling out alternate causes).

How far Pratkanis is allowed to testify regarding causation depends on the claims in the cases for which he is offered and how that testimony comes in. Pratkanis has not been identified as a "most likely" witness for the B.B. trial in plaintiff's most recent disclosure. Dkt. No. 3062-5. If Pratkanis is called in B.B.'s trial, he will be allowed to discuss his causation analysis, including his analysis of the Bradford Hill factors. Depending on the substance of his testimony and his explanation at trial as to how he reached his causation opinions, that testimony could be subject to challenge post-trial if it becomes clear that the Bradford Hill factors are necessary to sustain Pratkanis's causation opinions but do not adequately map onto a marketing causation analysis. At this juncture, however, Pratkanis's causation analysis will not be excluded.

Finally, JLI seeks to exclude Pratkanis' opinions about what JLI intended regarding marketing as impermissible intent and state of mind testimony. Br. #4 at 16:11-25; Reply Br. #4 at 19:12-18 (citing Pratkanis Report at 5). DENIED, consistent with the guidance above.

2. Altria

Altria argues that there is no basis for Pratkanis's opinion that Altria significantly increased distribution and availability of JUUL, further fueling the youth vaping epidemic, and that its role in the "Make the Switch" campaign somehow contributed to youth use. Altria points out (consistent with its challenges to Drumwright and Jackler) that Pratkanis performed no empirical study or analysis as a basis for his opinions. For example, he did not analyze the number of youth purchases at any store supplied by Altria or where Altria provided shelf space. As above, these arguments go to weight, not admissibility.

Altria separately challenges Pratkanis' qualification as an experimental social psychologist to opine on marketing, supply chain management "or any other subject that would render [him] capable of determining whether the Altria Defendants' conduct caused an increase in JUUL sales or use by underaged used, including B.B." Altria MTE at 11. Given his areas of expertise, Pratkanis is qualified. DENIED.

Q. Dr. Judith Prochaska

Dr. Judith J. Prochaska is a clinical psychologist with a master's degree of Public Health. She is the director of Stanford University Center's Tobacco Treatment Service, where she treats patients suffering from nicotine addiction. She offers opinions primarily related to the effects to youth from nicotine exposure and JLI's contribution to the youth vaping epidemic in her generic and B.B.-specific reports (JLI Exs. 18-19, Dkt. Nos. 2699-7 & 2699-8).

1. JLI

JLI seeks to exclude Prochaska's opinions regarding the allegedly inapposite MSA or other inapplicable laws, arguing as well that Prochaska misapplies the applicable standards. Roadmap at 17:5-13; Br. #1 at 52:11-54:9; Br. #2 at 3:18-21, 5:22-13:3; Reply Br. #1 at 39:12-43:6; Reply Br. #2 at 4:15-9:18 (citing Prochaska Report at 6-7, 29, 59-61, 89). DENIED, consistent with the discussion and guidance provided above.

JLI objects to Prochaska's unsupported opinions regarding additional design features, early research, and quality control and manufacturing. Roadmap at 16:15-17:4; Br. #1 at 25:1-26:23, Br. #5 at 9:22-12:5, 13:15-17:2; Reply Br. #5 at 10:6-15:2 (citing Prochaska Report at 53-57).

DENIED, as she has adequately identified the bases for her opinions.

JLI seeks to exclude Prochaska's opinions that JUUL products were defective and unreasonably dangerous, that JLI was sold "without authorization," and that JLI's packaging is misleading as impermissible legal conclusions. Br. #4 at 33:21-34:11 (citing Prochaska Report at 4-6, 68). DENIED, consistent with the guidance provided above and in the Order on the B.B. motions in limine.

JLI objects to Prochaska's opinions concerning what it intended regarding its marketing and product design as impermissible intent and state of mind testimony. Br. #4 at 19:18-20:5; Reply Br. #4 at 20:9-13, 22:8-21 (citing Prochaska Report at 5-7, 12, 55-59). DENIED, consistent with the guidance above.

JLI contends that Prochaska does not provide a reliable assessment or identify reliable evidence in support of her opinions regarding consumer perception of JUUL advertisements or that JUUL's design was intended to and did target youth. Br. #1 at 10:5-16:18, 24:7-14; Reply Br. #1 at 17:13-24:8 (citing Prochaska Report at 6, 17, 36-48, 59-67). DENIED. Prochaska sufficiently identifies the bases for her opinions on these topics, including the design elements used by JLI and the research supporting how those elements were uniquely attractive to youth.

JLI seeks to exclude Prochaska's general youth causation and B.B.-specific causation opinions as lacking in an accepted methodology and unreliable. Br. #1 at 28:20-49:16, 49:19-51:28; Reply Br. #1 at 29:21-23, 37:10-39:2 (citing Prochaska Report at 12, 28-35, 71-83). Prochaska did not merely "synthesize" others' research. She has explained the adequate bases for her general and B.B.-specific opinions regarding JLI's conduct, JUUL's design, and those impacts on youth generally and B.B. specifically. DENIED.

JLI contends that Prochaska's abuse liability comparisons to cigarettes and her addictiveness opinions based on product misuse are unsupported and unreliable. Br. #2 at 13:10-17:2; Reply Br. #2 at 9:20-11:11 (citing Prochaska Report at 4, 16, 36-48, 50-51, 54-55). Abuse liability compared to cigarettes is one relevant comparison, as is the comparison between abuse liability of JUUL and other ENDS or forms of nicotine replacement therapies ("NRTs"), and Prochaska has provided sufficient bases for her opinions. She need not have shown that JUUL

products are more addictive than cigarettes for her opinions to be relevant and admissible. Similarly, she has identified the basis for her testimony regarding nicotine and product misuse, evidence that JLI was aware of if not encouraging of that conduct, and sufficient support for her variable reinforcement opinions. DENIED.

JLI challenges Prochaska's general injury causation conclusions for lacking methodology and unreliability. Br. #3 at 22:2-27, 30:9-19; Reply Br. #3 at 15:9-20:8, 24:13-25:10 (citing Prochaska 13, 39). DENIED, as explained above, with respect to the injures left in play for B.B. – impaired brain development, anxiety, and mood and behavior disorders.

JLI contends that Prochaska's opinions about medical monitoring for B.B. are unreliable because she admits research is "still early" regarding whether long-term youth vaping leads to other substance abuse. Br. #3 at 30:9-19; Reply Br. #3 at 24:13-25:10) (citing Prochaska Report at 13). DENIED. This is a ground for cross-examination, not exclusion.

JLI objects to Prochaska's testimony regarding nicotine addiction warnings as preempted and therefore lacking fit. Br. #5 at 3:18-4:7 (citing Prochaska Report at 68-71). DENIED.

2. Altria

Altria objects to Prochaska's opinions that defendants' conduct sustained B.B.'s addiction and that B.B.'s initiation of JUUL was a natural and foreseeable consequence of defendants conduct, as failing to connect any Altria conduct specifically to B.B's injuries. Prochaska's B.B. specific opinions that Altria contributed to her addiction are based on documents indicating that Altria had extensive knowledge of JUUL use by youth and that by expanding sales for JLI, Altria contributed to that use by youth generally and B.B. specifically because each pod B.B. used after Altria started providing services contributed to her addiction and injuries. Altria's arguments raise grounds for cross-examination, not exclusion.

Altria separately argues that Prochaska's qualification as a clinical psychologist is insufficient for her to opine on marketing, supply chain management, "or any other subject that would render [her] capable of determining whether the Altria Defendants' conduct caused an increase in JUUL sales or use by underaged users" including B.B. Altria MTE at 11-12. That argument ignores Prochaska's extensive experience in studying the impact of tobacco marketing

and patterns of use, as well as her experience in tobacco control and use prevention. DENIED.

R. Dr. Robert Proctor

Dr. Robert N. Proctor is currently a Professor of the History of Science at Stanford University, as well as a Professor, by courtesy, of Pulmonary and Critical Care Medicine. He has published on the history of cancer, tobacco, and adverse health effects caused by cigarettes, as well as the history of the growth of knowledge of tobacco-cancer links. He has been qualified as an expert witness and testified on behalf of plaintiffs at trial in over 200 cases against tobacco companies. JLI Ex. 20, Dkt. No. 2699-9. He opines in this case on "deceptions" created by JLI and Altria through the advertising of JUUL and harms related to JUUL use, as well as the inadequacy of testing JUUL prior to releasing it on the market, and analyzes JLI's marketing tactics by comparing them with "Big Tobacco" techniques.

1. JLI

JLI moves to exclude Proctor's opinions regarding the allegedly inapposite MSA and other inapplicable laws. Roadmap at 17:5-13; Br. #1 at 52:11-54:9; Reply Br. #1 at 39:12-43:6 (citing Proctor Report at 41). DENIED, without prejudice to being reraised at trial and subject to a limiting instruction if Proctor mischaracterizes the MSA or other laws consistent with the guidance above.

JLI objects to Proctor's opinions regarding youth causation and marketing more generally as lacking in methodology and unreliable. Br. #1 at 26:25-28:17, 28:20-49:16; Reply Br. #1 at 30:9-31:5 (citing Proctor Report at 9, 14-64, 88). DENIED, consistent with above. JLI may cross-examine Proctor on how his prior tobacco-research applies to ENDS generally or JUUL specifically (as well as Proctor's reliance on ENDS research that was not JUUL-specific).

JLI also moves to exclude Proctor's opinions regarding the history of JUUL within the history of tobacco industry as an unduly prejudicial narrative about other companies in another industry based on hearsay books. Br. #4 at 5:12-8:20; Br. #1 at 26:25-28:17; Reply Br. #4 at 3:6-7:13, 7:22-10:13 (citing essentially the whole of Proctor Report). The issue of the books and their titles has been addressed in connection with defendants' motions in limine for the B.B. trial. JLI's objections based on fact narration and prejudice are otherwise DENIED. As noted in connection

with the order on the motions in limine for the B.B. trial, some limited historical background will be allowed to provide context for the jury.[44]

JLI objects to Proctor's opinion that JLI was "reckless, unreasonable, and negligent" in marketing and product design as impermissible legal conclusion. Br. #4 at 34:12-25 (citing Proctor Report at 10, 59-60. 82-84). Consistent with the guidance provided above and in the Order on the B.B. motions in limine, JLI's motion to exclude is DENIED.

JLI argues Proctor is not qualified to testify regarding corporate governance. Br. #4 at 24:1-6 (citing Proctor Report at 10). DENIED.

JLI objects to Proctor's testimony about what JLI intended regarded its marketing, product designs, and youth prevention as impermissible intent and state of mind testimony. Br. #4 at 23:14-24:6 (citing Proctor Report as 4, 8, 33, 37, 43, 45, 49, 56-57, 72, 84). DENIED, consistent with the guidance provided above.

2. ODDs

Separate from objections to Proctor's potential testimony addressed above regarding his lack of qualifications to opine on principles of corporate governance, allegedly impermissible legal conclusions, and providing only improper and unreliable narrative, the ODDs make a more targeted objection to Proctor's alleged attempts to malign the ODDs and his use of unduly prejudicial adjectives. ODDs MTE at 28-30. Specifically, the ODD's object to Proctor's personal opinions that the ODDs are "miscreants," his analogies to "Breaking Bad," and references to conspiracies and "nefarious" conduct. *Id*. Plaintiffs agree that Proctor will not use the objectionable phrases or analogies. *See* Pls. Omnibus Oppo. at 244 n.108. Besides that, the ODDs' request that Proctor not comment on their wealth is DENIED, subject to objections at trial, as long as any testimony connected to the financial gain each of the ODDs received from the Altria deal appears relevant to their motivations.

[44] JLI points to instances where Proctor's trial testimony was excluded or identified as potentially prejudicial. Consistent with the guidance in this Order and in the motions in limine for the B.B. trial, all experts should refrain from using unduly prejudicial or pejorative terminology.

3. Founder and Directors

Monsees moves to exclude the opinions of Proctor that Monsees gave "misleading" testimony to Congress and engaged in irresponsible corporate behavior as inappropriate credibility and legal conclusions reserved for the jury. Monsees' MTE at 4. Monsees (or another defendant) may object to this testimony at trial; whether it is appropriate depends on the foundation, context, and purpose of that testimony.

Bowen also specifically objects to Proctor's opinions about corporate conduct as outside his area expertise (addressed above), Proctor's use of pejorative or unduly prejudicial adjectives (addressed above), and finally to Proctor's testimony about Bowen's "intent." Bowen MTE at 3. Intent testimony will generally be allowed where it does not implicate ultimate issues of fact or law and has some basis in the evidence, and is not based on pure speculation.

S. Dr. Charles Pue

Dr. Charles Pue is a pulmonologist who opines that JUUL aerosol and vapor can cause or contribute to lung disease. He is an attending physician in the Pulmonary and Critical Care Division of Sarasota Memorial Hospital, a Clinical Assistant Professor of Medicine at Florida State University, and the clinical instructor at two schools of medicine, Florida State University and Lake Erie College of Medicine. JLI Ex. 21, Pue Report at 1 [Dkt. No. 2699-10]. He is also the Clinical Trials Investigator for the Clinical Research Center at Sarasota Memorial Hospital. *Id*. at 1. Dr. Pue has experience treating patients with lung injuries who were exposed to chemicals in the JUUL aerosol (including diacetyl), and in 2017 he reported one of the earliest identified cases of acute lung injury caused by vaping. *Id*. at 2.

JLI moves to exclude Pue's "unreliable" application of a flawed toxicology analysis. Ex. 21 p. 19 (Br. #3 at 6:1-10:21, 17:3-18:15; Reply Br. #3 at 4:8-15:6). DENIED, as explained above.[45]

[45] JLI also challenges Pue's opinions on general causation regarding lung injury, asthma and EVALI as lacking in methodology and unreliable. Br. #3 at 18:17-21:10; Reply Br. #3 at 15:9-20:8 (citing Pue Report at 1, 5, 10-11, 14-16, 19-20, 23-29). Those conditions are no longer at issue in B.B.'s case and have been deferred.

T. Dr. Kurt Ribisl

Dr. Kurt Ribisl serves as the Chair of the Department of Health Behavior at the University of North Carolina, Gillings School of Global Public Health, and is a tobacco regulatory science expert with a focus on sales and marketing of tobacco products at retail and online vendors. In his 25 years of experience in tobacco control policy research, he has authored over 160 scientific articles in the field and has been affiliated with many federal agencies, serving as the principal investigator on tobacco control research grants from the National Institutes of Health and Centers for Disease Control, among other federal agencies, and as a contributing author to three United States Surgeon's General reports on tobacco use including: Preventing Tobacco Use Among Youth and Young Adults (2012), E-cigarette Use Among Youth and Young Adults (2016), and a report that is currently being developed. Ribisl opines about JLI's youth prevention practices related to age and identity verification of purchasers at retail stores and online, and JLI's marketing of their devices.

JLI argues that Ribisl's testimony regarding its age verification and youth prevention efforts should be excluded as unnecessary fact narration. Br. #4 at 12:4-9; Reply Brief #4 at 12:17-14:7 (citing Ribisl Report 10-50). DENIED.

JLI also objects to Ribisl's opinions regarding what it knew regarding age verification as impermissible state of mind or intent testimony. Br. #4 at 22:22-23:12; Reply Br. #4 at 21:25-22:7 (citing Ribisl Report at 5, 10, 48-49, 77, 97). DENIED, consistent with the guidance provided above.

Finally, JLI contends that Ribisl's personal opinions regarding youth prevention are unreliable because "excerpting and screenshotting documents without any analysis is not a reliable expert methodology." Br. #4 at 12:4-9; Br. #1 at 54:11-57:25; Reply Br. #1 at 44:17-45:12 (citing Ribisl Report at 10-50). DENIED. Whether the documents at issue support his relevant opinions is grounds for cross-examination, not exclusion.

U. Dr. Alan Shihadeh

Dr. Shihadeh, founder of the American University of Beirut's Aerosol Research Laboratory, is an MIT-trained mechanical engineer who has long studied ENDS products,

including toxicant emissions, human puffing behaviors, aerosol generation and sampling, and related nicotine pharmacokinetics. Shihadeh Report [JLI Ex. 23, Dkt. No. 2699-12] at 2-4. His research into novel tobacco products, including ENDS, has been funded with support from the NIH and FDA. *Id*. Dr. Shihadeh serves as a scientific expert to the World Health Organization's Study Group on Tobacco Product Regulation. *Id*. As an expert on device engineering and design, human puffing behaviors, and aerosol analysis, he has extensively published on how design choices can impact aerosol — and nicotine — emissions. *Id*. at 2-4. He also has studied and opines upon the pharmacological relationship between nicotine emissions of tobacco products and blood-level exposure in users. *Id*.

Shihadeh discusses how and why JUUL's design informs consumer use patterns that reflect its high abuse liability. *Id*. Dr. Shihadeh characterizes JUUL's performance, including the physical and sensory aspects and pharmacokinetic consequences of JUUL's seemingly mild but "extraordinarily potent" nicotine delivery. *Id*.

Initially, JLI challenges Shihadeh's opinions that JUUL's design was intended to or did target youth and testimony regarding other possible design features as not based on reliable evidence or otherwise supported. Br. #1 at 24:3-6, 25:1-26:23; Reply Br. #1 at 17:13-24:8 (citing Shihadeh Report at 53-55). DENIED; these raise matters for cross-examination, not exclusion.

JLI objects to Shihadeh's youth causation opinions as lacking in methodology and as unreliable. Br. #1 at 28:20-49:16 (citing Shihadeh Report at 51). Shihadeh has identified sufficient bases for his opinions on how JUUL's design and formulation caused youth-uptake and addiction. DENIED.

JLI argues that Shihadeh misapplies the TCA standard by failing to assess JUUL as a switching product and fails to conduct a full abuse liability assessment, and thus all of his opinions, including abuse liability comparisons to cigarettes, should be excluded. Br. #2 at 3:18-21, 5:13-20, 5:22-13:3, 9:20-10:14,13:10-17:2; Reply Br. #2 at 2:4-4:13, 4:15-9:18, 9:20-10:14 (citing Shihadeh Report in full). Similarly, JLI challenges as unreliable Shihadeh's addictiveness opinions based on alleged product misuse. Br. #2 at 14:10-21; Reply Brief #2 at 10:15-11:11 (citing Shihadeh Report at 30). For reasons addressed above and because Shihadeh has identified

sufficient bases for his product misuse observations in support of his abuse liability opinions, these objections are DENIED. He may be cross-examined on those and his variable reinforcement opinions at trial.

JLI moves to exclude Shihadeh's opinions that JUUL products are defective and unreasonably dangerous as impermissible legal conclusions. Br. #4 at 33:1-11 (citing Shihadeh Report at 17, 50, 57). DENIED, consistent with the guidance provided in the Order on the B.B. motions in limine.

JLI also seeks to exclude Shihadeh's opinions about what JLI intended regarding its product design as impermissible state of mind and intent testimony. Br. #4 at 21:16-20; Reply Br. #4 at 20:26-21:2 (citing Shihadeh Report at 24, 39). DENIED, consistent with the guidance provided above.

Finally, JLI challenges as unsupported Shihadeh's opinions regarding early research and quality control/manufacturing. Br. #5 at 9:22-12:5, 15:7-19:7; Reply Br. #5 at 10:6-15:2 (citing Shihadeh Report at 19-22, 26, 51-52). DENIED; these are grounds for cross-examination, but not exclusion.[46]

V. Dr. Randall Tackett

Dr. Randall Tackett is a tenured professor of Toxicology and Pharmacology at the University of Georgia who opines about the chemicals in the JUUL aerosol, their toxicological profiles, and health risks to users of the JUUL products. JLI Ex. 24, Dkt. No. 2699-13.

JLI objects to Tackett's opinions on warnings/labels for lack of expertise. Br. #5 at 7:13-8:6 (citing Tackett Report at 54-55). DENIED. Tackett does not opine on how JLI should have drafted or conveyed potential warnings, but instead that JLI should have warned consumers about health effects but did not. That testimony is within his area of expertise.

JLI also objects to Tackett's opinions on whether JLI was required to include a health effects warning as an impermissible legal conclusion. Br. #5 at 4:26-6:12; Reply Br. #5 at 2:17-

[46] Altria moved to exclude Shihadeh's opinions concerning its conduct but did not address him on reply because plaintiffs are not seeking to offer his opinions against Altria. Pls. Omnibus Oppo. at 224 n. 101.

5:25) (citing Tackett Report at 54). DENIED, consistent with guidance provided above.

JLI contends that Tackett's opinion regarding early research is unsupported. Br. #5 at 12:17-13:14; Reply Br. #5 at 10:6-15:2 (citing Tackett Report at 20-21, 28-31, 33, 41-42). DENIED; this is a matter for cross-examination, not exclusion.[47]

Finally, JLI argues Tackett's opinions regarding health effect that were not included in warnings should be exclude because they are not based on reliable evidence. Br. #5 at 7:5-12; Reply Br. #5 at 6:2-16 (citing Tackett Report at 54-55). DENIED; this is a matter for cross-examination, not exclusion.

W. Dr. Jonathan Winickoff

Dr. Jonathan Winickoff is a pediatrician and an expert in youth tobacco control and public health who is currently the Director of Pediatric Research at the Massachusetts General Hospital (MGH) Tobacco Research and Treatment Center. He submitted generic and B.B.-specific expert reports (JLI Exs. 25-28; Dkt. Nos. 2693-10 – 2693-13, 2700-1) and opines about: the basic science of tobacco and nicotine; the physiologic vulnerability of youth to nicotine and nicotine addiction; the impact of youth nicotine use on mental health and progression to other drugs; pulmonary, cardiovascular and gastrointestinal effects of e-cigarette use; the youth e-cigarette epidemic; how the JUUL device delivers nicotine and fosters youth addiction; the impact of JUUL flavors on youth use; the abuse liability of JUUL products; JLI marketing that attracted youth; nicotine treatment and cessation strategies for youth; and, e-cigarette youth prevention strategies.

1. JLI

JLI moves to exclude Winickoff's opinions regarding the allegedly inapposite MSA and other inapplicable laws. Roadmap at 18:12-19:7; Br. #1 at 52:11-54:9; Reply Br. #1 at 39:12-43:6 (citing Winickoff Report at 64-66, 127). DENIED, consistent with the guidance above.

JLI contends that Winickoff's assessments of consumer perception of JUUL advertisements, whether JUUL's design was intended to or did target youth, and on additional

[47] JLI also challenges Tackett's general opinions on causation regarding asthma and EVALI as lacking in methodology and unreliable. Br. #3 at 8:1-10:21, 18:1-10, 20:8-20; Reply Br. #3 at 4:8-17:22 (citing Tackett Report at 4-6, 21, 23-27, 46, 54-56). Those conditions are no longer at issue in B.B.'s case and have been deferred.

design elements that were or should have been used, are excludable for lack of support and as not based on reliable evidence. Br. #1 at 10:5-16:18, 11:24-25, 24:15-25, 25:1-26:23; Reply Br. #1 at 17:13-24:8 (citing Winickoff Report at 128, 129, 168, 184, 199-210, 229-236). DENIED as matters for cross-examination, not exclusion.

JLI challenges Winickoff's general youth causation opinions for lack of methodology and as unreliable. Br. #1 at 28:20-49:16; Reply Br. #1 at 29:13-17 (citing Winickoff's Report at 10-11, 15, 126-133). DENIED. Winickoff did more than synthesize others' research in offering his causation opinions.

JLI moves to exclude Winickoff's testimony regarding the adequacy of JLI's duties regarding its disclosures, product design, and marketing as impermissible legal conclusions. Br. #4 at 31:14-32:14; Reply Br. #4 at 28:20-29:8 (citing Winickoff Report at 190-191, 194, 197, 205). Similarly, JLI moves to exclude opinions by Winickoff that are inappropriate legal conclusions regarding requirements for health effects warnings and where he discusses the allegedly inapposite MSA or other inapplicable laws. Roadmap at 16:15-24, 27:18-28:2; Br. #5 at 4:8-22, 7:5-12; Reply Br. #5 2:17-5:25 (citing Winickoff Report at 86, 173, 186, 199-210, 222). DENIED, consistent with the guidance provided in the Order on the parties' motions in limine and consistent with the guidance provided above.

JLI argues Winickoff's opinions regarding nicotine addiction warnings are preempted. Br. #5 at 1:26-4:22 (citing Winickoff Report at 26, 86, 186, 199, 209-10). DENIED.

JLI's challenges Winickoff's unsupported abuse liability comparison to cigarettes and nicotine toxicity opinions and his unreliable addictiveness opinions based on product misuse. Br. #2 at 13:10-17:2; Reply Br. #2 at 9:20-11:11; Br. #3 at 13:16-14:22, 15:23-16:8; Reply Br. #3 at 4:8-15:6 (citing Winickoff Report at 30-32, 36, 235-36). DENIED, for the reasons explained above.

JLI objects to Winickoff's opinions regarding what JLI intended regarding product design as improper state of mind and intent testimony. Br. #4 at 21:21-22:8; Reply Br. #4 at 21:2-5 (citing Winickoff Report at 95, 119, 120, 151, 171, 173, 183). DENIED, consistent with the guidance provided above.

JLI moves to exclude Winickoff's general injury testimony regarding impaired brain development, anxiety, and mood and behavior disorders, as lacking in methodology and unreliable. Br.#3 at 19:7-17, 20:21-22:27; Reply Br. #3 at 15:9-20:8 (citing Winickoff Report at 13-14, 20, 31-41). DENIED, for reasons discussed above.[48] As to the B.B.-specific injuries still at issue, JLI challenges Winickoff's opinions that B.B.'s nicotine addiction/JUUL use caused or contributed to her symptoms of depression, anxiety, mood swings, headaches and cognitive impairment. Br. #3 at 23:2-29:13; Reply Br. #3 at 20:22-24:11 (citing Winickoff Report at 4, 24). DENIED for reasons discussed above.

JLI's objections that Winickoff's medical monitoring opinions are unreliable concerning how B.B. requires more medical monitoring than what is required for her prior-existing conditions are DENIED. Br. #3 at 29:15-30:10 (citing Winickoff Report at 21-24).

Finally, JLI's argument that Winickoff's opinions regarding alleged health effects that were not included in warnings and opinions regarding quality control and manufacturing were unreliable and unsupported are DENIED, as matters for cross-examination and not exclusion. Br. #5 at 7:5-12, 17:3-23; Reply Br. #5 at 6:2-16 (citing Winickoff's Report at 115-120, 204-05).

2. Altria

Altria argues that Winickoff's opinions that Altria encouraged and assisted JLI with growing the nicotine/addiction market and increased youth sales are without basis generally (lacking any empirical basis) and there is even less basis for him to opine that non-specific Altria conduct contributed to B.B.'s nicotine dependence. Winickoff identified the documents he relies on to support his opinions regarding Altria's conduct (knowledge of youth JUUL use and that its efforts to support JUUL sales would have a negative impact on efforts to reduce youth use) and its likely impact on B.B. DENIED.

Altria separately challenges Winickoff's qualifications as a practicing pediatrician to opine on marketing, supply chain management "or any other subject that would render [him] capable of determining whether the Altria Defendants' conduct caused an increase in JUUL sales or use by

[48] Rulings on opinions on seizure, asthma, EVALI, and GERD have been deferred.

underaged used, including B.B." Altria MTE at 11-12. Altria ignores Dr. Winickoff's decades-long experience with tobacco control as well as tobacco marketing. DENIED.

3. Founder and Directors

Bowen objects to Winickoff's opinions about "shocking" conduct and "inappropriate" marketing practices as improper and prejudicial testimony, and likewise objects to his opinions as based on impermissible speculation about his or others' intent. Bowen MTE at 5-6. As noted above, intent testimony will generally be allowed where there is an evidentiary basis for it as long as that testimony does not invade the province of the jury on an ultimate legal question in a particular case for identified claims. While plaintiffs have been cautioned to instruct their experts to avoid unduly inflammatory or potentially prejudicial adjectives, whether use of a particular adjective is inappropriate is better determined in context at trial if an objection is made.

X. Dr. Samuel Woolley

Dr. Samuel Woolley is an assistant professor of journalism, media, and information at the University of Texas at Austin, the Fellow of the R.P. Doherty Professorship in Communication at UT Austin's Moody College of Communication, and the head of the Propaganda Research Lab and a Knight Foundation Faculty Fellow at the Center for Media Engagement at UT. He is proffered as an expert in how broadcast media, social media and emerging digital information communication technologies are used to influence human behavior. JLI Ex. 29, Dkt. No. 2700-5.

JLI argues that Woolley lacks expertise to opinion on tobacco regulation and standards for scientific research. Br. #4 at 10:19-11:4, 32:15-28 (citing Woolley Report at 5, 51-77, 88-89). DENIED.

JLI moves to exclude Woolley's summary of marketing documents as impermissible fact narration. Br. #4 at 10:19-11:4; Reply Br. #4 at 11:25-12:15 (citing Woolley Report at 10-77, DENIED, consistent with the guidance above. Woolley's opinions regarding JLI's-industry sponsored research are admissible and JLI's criticisms of his opinions provide grounds for cross-examination, not exclusion.

JLI contends that Woolley's opinions that it was irresponsible, unreasonable, and reckless

in marketing are excludable legal conclusions. Br. #4 at 32:15-28 (citing Woolley Report at 5, 88-89). DENIED, consistent with the guidance above and more specifically determined at trial based on claims at issue.

JLI objects to Woolley's opinions concerning what it intended with its marketing as impermissible intent and state of mind testimony. Br. #4 at 17:11-21; Reply Br. #4 at 19:19-24 (citing Woolley Report at 5, 11, 13, 15, 23, 27, 36, 39, 40, 88). DENIED, consistent with guidance provided above.

JLI argues Woolley's assessment of consumer perception of JUUL advertisements are unreliable and assessed under the wrong standards. Br. #1 at 10:5-16:18, 19:22, 20:4-13; Reply Br. #1 at 14:1-5 (citing Woolley Report at 4-6, 11-48). DENIED.

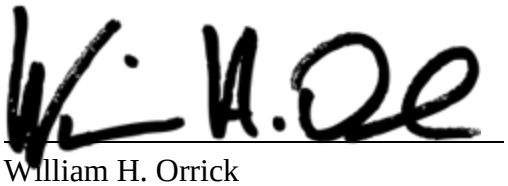
Finally, JLI objects to Woolley's general youth causation opinions (that JLI's marketing caused the spike in youth uptake through its intentionally viral social media efforts) for a lack of methodology and as being unreliable because he failed to conduct an empirical analysis or attempt to quantitatively measure the impact. Br. #1 at 28:20-49:16; Reply Br. #1 at 34:14-37:7 (citing Woolley Report at 35, 45-48). DENIED for reasons identified above.

III. MOTIONS TO SEAL

Within thirty days of the date of this Order, the parties shall meet and confer to submit one joint chart identifying what narrowly-tailored information submitted in connection with the motions to exclude should remain under seal under the compelling justifications standard. The parties shall take into account the Court's prior guidance on administrative motions to seal and consider what information is likely to be admitted and therefore publicly disclosed at the upcoming B.B. trial.

IT IS SO ORDERED.

Dated: June 2, 2022



William H. Orrick
United States District Judge